TO COMPARE ENDOTHELIAL CELL COUNT AT 1 YEAR BETWEEN FULL THICKNESS AND LAMELLAR CORNEAL TRANSPLANT

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Dedicated To
My Respected
Teachers, Family
&Friends

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Dr. Chandandeep Kaur Gill

LIST OF ABBREVIATIONS

BCVA	Best Corrected Visual Acuity
CCT	Central Corneal Thickness
DLEK	Deep Lamellar Endothelial Keratoplasty
DM	Descement Membrane
DMAEK	Descement Membrane Automated Endothelial Keratoplasty
DMEK	Descement Membrane Endothelial Keratoplasty
DSAEK	Descement Stripping Automated Endothelail Keratoplasty
DSEK	Descement Stripping Endothelial Keratoplasty
ECD	Endothelial Cell Density
FECD	Fuchs Endothelial Corneal Dystrophy
KCN	Keratoconus
PBK	Pseudophakic Bullous Keratopathy
PK	Penetrating Keratoplasty
PPCD	Posterior Polymorphous Corneal Dystrophy

ABSTRACT

Introduction: Full Thickness corneal transplant has been the standard treatment option for corneal replacement for many years. It is an established procedure whereas lamellar keratoplasty is relatively a newer procedure .Endothelial cell loss is common concern after corneal transplant of both full thickness and lamellar corneal transplant. Endothelial rejection can lead to endothelial cell damage and eventually, decrease the corneal transparency.

Aim of Study: To compare the endothelial cell counts in patients at 1 year follow up after Full thickness and Lamellar Corneal Transplant.

Materials & Methods: In this retroprospective study all patients with history of full thickness and lamellar corneal transplant presenting to the out patient services between January 2020 and December 2020 were recruited. All the subjects were to detailed slit lamp examination and endothelial cell count using specular microscopy. Results were compared between the two.

Results: Study involved 32 eyes in study group which was further divided into posterior lamellar keratoplasty and full thickness keratoplasty. Baseline mean ECD of the donor corneas used for the lamellar keratoplasty group was 2874±157.71cells/mm^2 and 1737.8±593 cells/mm^2 at 12 months. Baseline mean ECD of the donor cornea in full thickness keratoplasty cases was 2857±257.71 cells/mm^2 and at 12 months, it was found to be 1744±570.53 cells/mm^2. Difference between both the groups was not statistically significant.

Conclusion: Loss in endothelial cell density is more in lamellar keratoplasty as compared to full thickness keratoplasty at 12 months.

Keywords: Endothelial cell count, Lamellar keratoplasty, Full thickness keratoplasty

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INTRODUCTION

In developing countries, corneal diseases are one of the major public health problem. Corneal transplant is one of the most common surgical management done in these patients. As cornea is devoid of vasculature, therefore there is a minimal risk for graft rejection. Thus, it is the most successful organ transplantation in human body.

Corneal transplant was first performed by Zirm [1] in 1905 and since then, it has evolved from replacement of full thickness donor cornea to replacement of only the diseased layer of the cornea. It has been possible due to relentless efforts by researchers and advancements in technology in all these years.

Corneal transplant is broadly classified as full thickness penetrating keratoplasty and lamellar corneal transplant.

Cornea: Structure and Function

Cornea is a complex avascular transparent structure. It consists of six layers. The anterior most layer is epithelium. The second layer is Bowman's membrane. Stroma consists of a major part of cornea and it contains keratocytes and corneal lamellae whose fibrils are remarkably uniform in size. The crystalline organization and critical spacing of collagen fibrils makes cornea transparent [2]. Dua's layer is 10-15 microns in thickness and it provides base for endothelial cells. The innermost layer is corneal endothelium. Corneal endothelium plays a major role in maintaining the optical transparency of the cornea. Any accumulation of fluid would disrupt the spacing between the collagen fibrils and degrade the transparency of the cornea.

A healthy cornea has endothelial cell density (ECD) of 6000 cells/mm^2 in early neonatal period. There is physiological decline in endothelium cell density with age. Approximately 3500-3000 cells/mm^2 are found in cornea during early childhood due to normal growth in corneal size and concurrent cellular attrition **[2].** This decline in ECD is said to be physiological therefore does not affect the normal corneal functioning.

Bertelmann et al [3] conducted a study on risk factors for endothelial cell loss. The aim of this study was to determine the rate of endothelial cell loss in our patients and to detect dependencies on donor- and recipient-related factors. Using non-contact specular microscopy, endothelial cell counts were recorded every 6 months from 293 consecutive patients who underwent keratoplasty between 1996 and 2000.This study showed that preoperative glaucoma is a major risk factor for increased endothelial cell loss following keratoplasty.

In various diseases like Fuchs endothelial dystrophy or after intraocular surgeries, there can be accelerated loss of endothelial cell density, more than the expected natural course of physiological endothelial cell loss at that age.

There are various parameters that are required to be evaluated before planning the corneal transplant. When loss in ECD is below 500-600 cells/mm^2, it can compromise the endothelial function of the cornea. After this, cornea loses its transparency, due to corneal edema and ultimately, leads to visual impairment.

Human corneal endothelial cells are unable to spontaneously divide and regenerate under physiological conditions [4]. In early gestational period, endothelial cells are believed to be locked in the quiescent G1 phase of the cell cycle [5].

Following are the natural responses of the corneal endothelial cells in diseased states

a) Cell enlargement
b) Cell redistribution and migration to replace the damaged endothelial cells.

The current approach to deal with endothelial failure relies on the replenishment by an exogenous source of healthy endothelial cells through various techniques of corneal transplantation [6]. Corneal transplant may be classified on the basis of indication for which it is done such as therapeutic or tectonic. Another classification is on the

basis of the diseased corneal layer that is required to be replaced by donor corneal layer. Thus in this classification, corneal transplant is broadly classified as full thickness penetrating keratoplasty, anterior and posterior lamellar keratoplasty.

Full thickness keratoplasty is a surgical technique to replace the full thickness of cornea with donor cornea. After deciding the appropriate size of trephine and donor punch, preparation and punch of the donor tissue is done. The host cornea is cut with corneal scissors and donor button is applied over the recipient's eye with endothelial side down. Then, cornea is sutured in place using interrupted or continuous sutures. All the suture knots are buried and eye is patched. Intra operative complications of full thickness keratoplasty are namely, poor graft centration, irregular trephination, damage to the lens, damage to the donor tissue and choroidal haemorrhage and effusion. Post-operative complications include wound leak, glaucoma, endophthalmitis, persistent epithelial defect, microbial keratitis and graft failure.

Lamellar keratoplasty has various advantages over full thickness in terms of less intraoperative complications, maintaining globe integrity and less chances of graft rejection in post-operative period.

Anterior lamellar keratoplasty-

In 1948, Paufique brought back anterior lamellar keratoplasty and microkeratome was introduced by Barraquer [7]. Microkeratome gives more regular cut as compared to manual method and thus it provides better visual gain than manual assissted anterior lamellar keratoplasty. Anterior lamellar keratoplasty is further divided into superficial and deep lamellar keratoplasty.

Superficial anterior lamellar keratoplasty is used to treat corneal disease involving anterior 30-40% of the cornea. It is mainly indicated for superficial scars as a result of healed keratitis, trachoma and trauma. It can also be done in some corneal dystrophies and degenerations.

Deep anterior lamellar keratoplasty is performed in cases of deep corneal opacities with healthy endothelium. Other indications are keratoconus and stromal dystrophies.

Posterior lamellar keratoplasty –

In this procedure, endothelium is replaced by healthy donor tissue, thus used to treat only those diseases which involve endothelium and rest of the cornea is not affected.

Diseases like Fuchs endothelial corneal dystrophy (FECD), posterior polymorphous corneal dystrophy (PPCD), congenital hereditary endothelial dystrophy (CHED), iridocorneal endothelial syndrome (ICE), viral endothelial dysfunction; aphakic bullous keratopathy (ABK) and pseudophakic bullous keratopathy (PBK) may require posterior lamellar keratoplasty. Descement membrane stripping endothelial keratoplasty (DSEK) is a modified concept of host stromal dissection. It is introduced by Melles et al [8]. They described a technique for the excision of the Descemet membrane (DM) from the recipient eye for preparation of a recipient stromal bed in posterior lamellar keratoplasty. They took 10 human eye bank eyes and 3 patients. Recipient eyes had a 5.0-mm scleral tunnel incision made extending 1.0 mm into the peripheral cornea at the 12 o'clock surgical position. The anterior chamber was completely filled with air, and a reflective glide was placed through the incision onto the iris, to better visualize DM. A 9.0-mm mark was made onto the corneal epithelium to outline the area from which the Descemet membrane was to be removed. With a custom-made scraper, the DM was then carefully stripped off the posterior stroma by loosening the membrane at the 6 o'clock position and pulling it toward the incision at 12 o'clock. The excised DMs were evaluated by light and electron microscopy. This study concluded that with the technique described, DM can be excised in a controlled fashion without damaging the posterior corneal stroma, to quickly create a recipient stromal bed before implantation of a donor posterior lamellar disk in posterior lamellar keratoplasty. When Govroy et al [9] used

an automated microkeratome for donor dissection, DSEK became Descemet stripping automated endothelial keratoplasty (DSAEK).In 2006, Melles et al [8] again presented a breakthrough surgery that showed the technique of replacing only diseased endothelium with healthy endothelium. This technique is known as Descemet membrane endothelial keratoplasty (DMEK). In this technique, the descemet's membrane (DM) and endothelium were stripped from donor corneas submerged in corneal storage solution in a corneal viewing chamber. Donor DM diameters were 8.5 or 9.0 mm. The central 7 mm of DM was stripped from the recipient cornea. After staining with trypan blue to improve visualization, donor DM was inserted through a 2.8-mm incision. According to this study, DMEK provided a significantly higher rate of 20/20 and 20/25 vision, with comparable endothelial cell loss in case of DSAEK.

So, over the last decade, the surgical treatment for endothelial disease has rapidly evolved toward selective diseased corneal layer transplantation, and away from full-thickness penetrating keratoplasty (PK).

AIMS AND OBJECTIVES

- To evaluate the corneal endothelial cell density loss at 1 year in posterior lamellar and full thickness keratoplasty.
- To compare the endothelial cell density loss of posterior lamellar keratoplasty with full thickness keratoplasty at one year.

REVIEW OF LITRATURE

History of corneal transplant

The term “keratoplasty” is first described by Franz Reisinger in a publication in 1824 [10]. Earlier in 1800, further concepts were described by Astley Cooper, Karl Himly, Gottlieb Mossner and Samuel Bigger[10].
In 1840 first set of basic principles for keratoplasty was outlined by Michael Marcus. He described the principles of need for similar size of donor and recipient tissues, rapid transfer of donor tissue to host, attachment of donor tissue in a traumatic fashion. In same year, first aterior lamellar keratoplasty was described by Franz Muhlbaeur by using triangular-shaped lamellar graft. But most of these attempts of transplant were proved to be unsuccessful [**10**].

In 1878, G.F Sellerback performed the first human corneal transplant using simple manual trephine and given importance to the presence of healthy donor tissue.

In 1906, Eduard Zirm [1] performed first successful transplant. He performed this operation on patient with severe alkali burns. Donor was 11 year old boy. The donor tissue was removed by using 5mm trephine. It remained clear for at least 6.5 months. After this successful transplant, he described several fundamental principles of corneal transplant surgery. He gave emphasis on the exclusive use of healthy, human donor material, the employment of strict sterile technique, the protection of the graft with physiologic saline and avoidance of any toxic chemicals, the use of overlay sutures to secure the graft. The work of Ramon casterviejo had the most profound effect on modern day keratoplasty [**11**]. He studied keratoplasty in both clinical and laboratory settings. He progressed from use of square graft to a circular one and from traditional overlay sutures to direct appositional suturing. Other important events were occurring side by side, were the development of the operating microscope and the availability of monofilament nylon suture materials [12]. In 1945, first eye bank was established by R. Townley Paton which served as cornerstone for later de-

velopment of a national eye banking movement. Evolution of penetrating keratoplasty to lamellar keratoplasty in 1914, Anton Elsching first reported the successful lamellar keratoplasty in case of interstital keratitis. Subsequently, he reported case series of 174 cases and that inspired others such as Vladimir Filatov, Paufique and others.

Lamellar keratoplasty mostly evolved in 20th century due to advances made by Baraquer, Filatov and others.

After these technical and laboratory advancements, the goal of the surgery became not only successful transplant but also optical clarity, minimal astigmatism, improved predictability of corneal refractive power, ease of recovery and decreased rate of rejection[13]. Further, with increased understanding of pathophysiology came the realization that, in many cases, it might not be necessary to replace the entire cornea, but, in fact, it might be preferable to replace only the ”diseased” portion, maintaining the integrity of the host cornea as much as possible [14]. Therefore, for anterior stromal diseases, deep anterior lamellar keratoplasty (DALK) is most preferred surgery likewise for endothelial disorders, Descemet stripping automated endothelial keratoplasty (DSAEK) is being done these days.

PENETRATING KERATOPLASTY

Penetrating keratoplasty is a procedure in which host tissue of full thickness is replaced by donor tissue. Indications of penetrating keratoplasty are

1. To eliminate infection
2. To establish a clear visual axis
3. To minimize refractive error in cases of sverely distorted corneas
4. To provide tectonic support.

General considerations:

Donor tissue

Donor tissue should be taken within 6-12hours of death and stored in eye banks prior to transplantation. In eye banks, evaluation includes

medical history review and donor blood screening to exclude contraindications and microscopic examination of the cornea. Corneas are stored in various media under hypothermic conditions or in organ culture medium for up to 4 weeks.

Contraindications to cornea donation are

1. Death from unknown cause
2. Certain infections like HIV, viral hepatitis, tuberculosis, septicemia and active malaria
3. Patients with metastatic carcinomas
4. In some malignant ocular tumors
5. Corneal refractive surgeries.

Recipient factors

Following the various recipient factors that may adversely affect the prognosis of corneal graft

1. Severe stromal vascularisation
2. Active corneal inflammation
3. Abnormalities of eyelids such as blepharitis, ectropion, entropion and trichiasis
4. Recurrent or progressive forms of conjunctival inflammation such as ocular cicatricial pemphigoid.
5. Anterior synechiae
6. Uveitis
7. Uncontrolled glaucoma

Surgical steps in penetrating keratoplasty

1. Insertion of proper sized lid speculum and there should be minimal pressure against the globe.
2. Marking of the host cornea done by surgeon using possible centre of the cornea.
3. Trephination of host cornea with endothelial side up using sharp trephine. Well cut round donor tissue is obtained without traumatising the endothelium. Prepared donor cornea is kept submerged in storage medium.

4. Host cornea is trephined using sharp trephine without giving undue pressure over trephine. Trephine must be progressively rotated, so as to penetrate its sharp edges upto pre-descement membrane.
5. Viscoelastic is used to fill the anterior chamber to maintain anterior chamber stability
6. Donor tissue is placed over in the host bed by using toothed forceps without injuring the endothelium
7. 4 cardinal sutures are placed by proper suturing techniques to prevent wound gape. Bowman to bowman apposition needs to be achieved
8. Other sutures are taken and knots are buried and are kept far away from the limbus.

ANTERIOR LAMELLAR KERATOPLASTY

In anterior lamellar keratoplasty, diseased corneal stroma is replaced partially or totally by donor tissue leaving endothelium intact.

Following are the indications

1. For tectonic support in desmetocele, pellucid marginal degeneration and sterile mooren ulcer.
2. In ectatic disorders like keratoconus, epithelial and stromal dystrophies and degenerations to clear visual axis
3. For cosmetic reasons as in cases of corneal opacity. Contraindications are if endothelium is unhealthy or there is any break in descement membrane as in post hydrops cases.

Surgical techniques

1. After a partial thickness trephination, superficial stroma is excised by manual lamellar dissection. This dissection technique is known as layer by layer method
2. Stromal delamination - In this injection of air or balanced salt solution is used into deep stroma using 27-30 gauge needle. After using air, stroma turns white and then dissection is carried out in layers.
3. Automated lamellar keratoplasty can be done by using micro keratome or femtosecond laser.

ENDOTHELIAL KERATOPLASTY

Following are the indications

1. Patients with endothelial dystrophies such as Fuchs endothelial dystrophy, posterior polymorphous dsytrophy.
2. Cases with endothelial dysfunction like aphakic and pseudophakic bullous keratopathy, irido-corneal endothelial syndrome or prior ocular surgery.

Contraindications are

1. Stromal opacity or scarring
2. Leratoconus
3. Hypotony

Advantages of endothelial keratoplasty are rapid visual recovery as the vision stabilizes within 3 months of surgery. Moreover, there is no astigmatism and therefore no shift in refractive error.

Types of endothelial keratoplasty procedures

1. Descement stripping endothelial keratoplasty (DSEK)- In this technique, Descemet membrane and endothelium are stripped from recipient cornea and the partial thickness donor button placed on the posterior surface of the stripped recipient corneal stroma.
2. Descemet stripping automated endothelial keratoplasty (DSAEK) - it is similar to DSEK but microkeratome is used for donor tissue trephination.
3. Descemet membrane endothelial keratoplasty (DMEK)-in this, Descement membrane and endothelium are replaced. It is more challenging than conventional DSAEK.
4. Descemet membrane automated endothelial keratoplasty (DMAEK) - automated version of DMEK. It is best of all the techniques.

Donor preparation for Endothelial keratoplasty Donor can be prepared by manual dissection or by automated keratome dissection for DSAEK. In manual dissection, around 16mm of scleral rim is required around the donor cornea so as to secure the tissue into an artifial anterior chamber. Materials like viscoelastic or BSS can be used for endothelium protection and maintainence of anterior chamber. Femtosecond laser can also be used to prepare donor tissue

Surgical techniques for DSEK

1. Epithelium is marked, then one to three paracentesis incisions are made. After that, incisions into anterior chamber are created.
2. Recipient preparation is done by stripping of the decement membrane and endothelium after putting viscoelastic in anterior chamber.

3. Reverse sinkey is used to score the endothelium and decement membrane inside the marked incisions.
4. When 360 degree scoring of endothelium/DM complex is completed, the host tissue is removed.
5. Various techniques can be used for donor insertion. Taco like configuration can be used. Other techniques are compression forceps, burrito configuration.
6. The Rosenwasser shovel is an instrument used to deliver the donor. Tissue is placed over it with stromal side down after pouring viscoelastic over it. It is then inserted inside.
7. Various donor glides and inserters are also available these days for the delivery of donor tissue. Sheet glide is the technique which is used in this study for the patients of DSEK. Compared to PKP, sheet glides DSAEK had better endothelial cell density at 3 years [15].
8. Two or 4 sutures are required to close the wound created.

CHANGING TRENDS: Shift from Penetrating Keratoplasty to Lamellar Keratoplasty

Zhang et al [16] evaluated trends in indications for and preferred surgical techniques of corneal transplantation in Ontario over a 12-year period. They found that found a significant decrease in the number of PKP and an increase in DSAEK and DALK since the introduction of lamellar keratoplasty in 2006. FECD was managed by DSAEK in 83 per cent cases and PKP in 13 per cent in 2011-2012.

Ryan Le [17] evaluated the current surgical approaches at the University of Toronto and found that 61 per cent of keratoplasties were LK and 39 per cent underwent full-thickness PKP. Amongst the lamellar procedures, DSAEK accounted for most of the surgeries (68%) followed equally by DALK (16%) and DMEK (16%).

Zare et al[18]found the most common surgical technique to be PKP (70.9%), followed by DALK (20.1%) and DSAEK (2.3%) during their study period of six years .However, over the study period, there was a

significant decrease in the number of PKP and increase in lamellar keratoplasty.

Park et al [19] in teir 10 yr review found that there was an increase in the total number of corneal transplants from 2005 to 2014. In the last decade of their study, PKP was found to decrease significantly (from 95 to 42%) and an increase in LK techniques (from 5 to 58%) was seen. DSAEK was the most common (50%) type of corneal transplantation performed in the United States in 2014. The volume of DMEK was found to be doubling every year since 2011.About 75 per cent of cases of corneal decompensation were managed by EK in 2014. EK was the treatment of choice for more than 90 per cent cases of FECD and for 60 per cent of PBK cases; while PKP was being done for 40 per cent of cases of PBK.

ENDOTHELIAL CELL COUNTS IN KERATOPLASTY

Ku Bl et al [20] conducted a study to compare endothelial cell density (ECD) loss rates in penetrating keratoplasty (PKP), Descemet's stripping automated endothelial keratoplasty (DSAEK), and deep anterior lamellar keratoplasty (DALK).Patients who received PKP, DSAEK, or DALK from 2009 to 2014 were analyzed (68 vs. 38 vs. 11 patients, respectively). Only clear grafts and initial ECD more than 1000 cell/mm2 were included in the study. The main outcome was ECD loss rate. The follow-up time period was divided into five subgroups: 0-1.5 months, 1.5-6 months, 6-12 months, 12-24 months, and longer than 24 months. According to the study Although ECD loss rate in the DSAEK group was initially larger than that in the PKP group, the DSAEK group possessed better long-term endothelial cell survival rate. The DALK group had a lower ECD loss rate than that of the other groups and maintained a stable ECD at 1 year after surgery.

Bart Van Dooren et al [21]conducted a study to report the midterm endothelial cell density measurements after posterior lamellar keratoplasty (Melles techniques).Fifteen consecutive eyes of 15 patients in whom a posterior lamellar keratoplasty procedure was performed for

pseudophakic bullous keratopathy or Fuchs' endothelial dystrophy were evaluated. In 11 corneas the donor tissue was inserted through a 9.0-mm sclerocorneal pocket incision (technique A). in four cases the donor was folded and inserted through a 5.0-mm incision (technique B). Specular microscopy was performed at 6, 12, 24, and 36 months after surgery, to measure the endothelial cell density. Study concluded that in posterior lamellar keratoplasty, the donor corneal endothelium showed a decrease in cell density similar to that after conventional full-thickness penetrating keratoplasty.

Marcus Ang et al [22] studied endothelial cell loss and graft survival after Descemet's stripping automated endothelial keratoplasty and penetrating keratoplasty. Study design was Retrospective, nested, cohort study. Consecutive patients who underwent DSAEK or PK with Fuchs' endothelial dystrophy or pseudophakic and aphakic bullous keratopathy (BK) at a single tertiary center from April 1, 2006, to April 1,2008. Clinical data and donor and recipient characteristics were recorded from our prospective cohort from the Singapore Corneal Transplant Study. Main outcome was percent EC loss and graft survival up to 3 years. In results, there were no differences in baseline characteristics of patients comparing DSAEK and PK. there were more patients with BK than Fuchs' dystrophy. Percent EC loss was lower in DSAEK compared with PK at 1, 2, and 3 years postoperatively. Graft survival was comparable between DSAEK and PK at 1, 2, and 3 years. This study concluded that DSAEK resulted in lower endothelial cell loss with comparable cumulative graft survival rates for up to 3 years in patients with Fuchs' dystrophy and BK.

Banu Torun Acar et al **[23]** studied changes in endothelial cell density following penetrating keratoplasty and deep anterior lamellar keratoplasty. The study included 44 and 54 patients treated with PK and DALK, respectively, between March 2006 and April 2010. Corneal ECD was examined using specular microscopy at postoperative 1, 3, 6, 12, and 18 months, and the values were compared. Results

showed that corneal ECD reduction in the PK group was 7.4%, 15.2%, 23.5%, and 28.9% at 3, 6, 12 and 18 months respectively after surgery, compared with 4.2 % in the first month. These figures were 3.0%, 6.7%, 7.2%, and 7.7% at 3, 6, 12 and 18 months respectively, compared with 2.2 % in the first month in the DALK group. These results suggest that survival of endothelial cells in grafts is better after DALK than after PK.

A report published by the American Academy of Ophthalmology [24] concluded that DALK is equivalent to PK for the outcome measure of BSCVA, particularly if the surgical technique yields minimal residual host stromal thickness. There is no advantage to DALK for refractive error outcomes. Although improved graft survival in DALK hasyet to be demonstrated, postoperative data indicate that DALK is superior to PK for preservation of ECD. Endothelial immune graft rejection cannot occur after DALK, which may simplify long-term management of DALK eyes compared with PK eyes. Objective of this report was to review the published literature on deep anterior lamellar keratoplasty (DALK) to compare DALK with penetrating keratoplasty (PK) for the outcomes of best spectacle-corrected visual acuity (BSCVA), refractive error, immune graft rejection, and graft survival.

W M Bourne et al [2] observed one year transplanted human corneal endothelium. In 34 penetrating corneal transplants, endothelial photographs were taken preoperatively and at four postoperative intervals; four days, three weeks, three months, and one year. Preoperative corneas from older donors had larger and more variably sized endothelial cells. Although the mean endothelial cell loss at the four day examination was only 17%, if continued at a linear rate so that by one year almost half of the central endothelial cells were gone. The continued cell loss was not significantly affected by the operative cell loss, the presence of a lens postoperatively, or the recipient endothelial status. Six of the 34 transplants sustained documented episodes of allograft rejection, but their endothelial cell losses were minimized by

prompt treatment with corticosteroids. The cell losses in the 20 phakic and 14 aphakic transplants were similar at both the four-day and one-year intervals, although the aphakic grafts were thicker at both times.

Anil kubaloglu et al [25] studied and compared the status of corneal endothelium and central corneal thickness within the first four post-operative years after deep anterior lamellar keratoplasty (DALK) and penetrating keratoplasty (PK) in patients with keratoconus. Thirty-nine eyes (Group A) which had PK and 44 eyes (Group B) which had DALK for the treatment of keratoconus were included in this retrospective study. The endothelial cell density (ECD), the mean endothelial cell area and the coefficient of variation of cell area were assessed with a non-contact specular microscope, and the central corneal thickness (CCT) was measured with an ultrasound pachymeter. This study concluded that corneal endothelial cell loss in the DALK group occurs at a slower rate than in the PK group suggests DALK as a safer alternative to PK in these selected patients.

Bertelmann et al [3] conducted a study on risk factors for endothelial cell loss. The aim of this study was to determine the rate of endothelial cellos in our patients and to detect dependencies on donor- and recipient-related factors. Using non-contact specular microscopy, endothelial cellcounts were ned every 6 months from 293 consecutive patients who underwent keratoplasty between 1996 and 2000. Follow-up time was 36 months. This study shows that preoperative glaucoma is a major risk factor for increased endothelial cell loss following keratoplasty.

Price Mo et al [26] conducted a study to assess 3-year outcomes of Descemet's stripping automated endothelial keratoplasty(DSAEK) in comparison with penetrating keratoplasty (PKP) from the Cornea Donor Study (CDS). The DSAEK procedures were performed by 2 experienced surgeons using the same donor and similar recipient criteria as for the CDS PKP procedures, performed by 68 surgeons. Graft success was assessed by Kaplan-Meier survival analysis. Central en-

dothelial cell density (ECD) was determined from baseline donor and postoperative central endothelial images by the reading center used in the CDS Secular Microscopy Ancillary Study. Study found that the graft success rate and endothelial cell loss were comparable at 3 years for DSAEK and PKP procedures. A 5-mm DSAEK incision width was associated with significantly less cell loss than a 3.2-mm incision.

Khattak A et al [27]conducted a study to assess to compare visual acuity, refraction, topography, and complications of deep anterior lamellar keratoplasty (DALK) and penetrating keratoplasty (PKP) performed in patients with keratoconus (KCN).In this retrospective interventional non-randomized clinical study, patients with moderate to severe KCN that underwent either PKP or DALK for optical corrections were enrolled. The final outcome analysis was performed after complete suture removal for both groups of patients. Best corrected visual acuity, spherical equivalent, refractive cylinder, average keratometry, corneal astigmatism, and endothelial cell density as well as early and late complications such as cataract, glaucoma, corneal edema, elevated intraocular pressure without visual field defect or optic disk changes, rejection, loose suture, and re-suturing were compared. According to this study the vision, refractive error, and corneal astigmatism following DALK and PKP were comparable; however, DALK had lower incidence of long-term complications.

According to Maier P et al [28] study in 2009, Deep anterior lamellar keratoplasty (DALK) avoids the risk of endothelial immune reactions. However, visual outcomes are comparable to PKP only is complete baring of Descemet's membrane is achieved. In Descemet stripping (automated) endothelial keratoplasty [DS(A)EK], a variation of posterior lamellar keratoplasty, only the diseased endothelium is removed with the Descetmet membrane (descemetorhexis). The lamellar, endothelium-bearing graft can subsequently be implanted via a corneoscleral/corneal tunnel, whereby little astigmatism is induced. The main advantage of DS(A)EK compared to PKP is faster visual recovery with

almost unaltered refraction, although visual acuity is often slightly lower.

Bahar I et al [29] conducted a study to describe the visual outcomes and intraoperative and postoperative complications after penetrating keratoplasty (PK), deep lamellar endothelial keratoplasty (DLEK), Descemet stripping endothelial keratoplasty (DSEK), and Descemet stripping automated endothelial keratoplasty (DSAEK) and to compare the results with those of previously reported series. One hundred seventy-seven eyes of 161 consecutive patients who had corneal edema resulting from Fuchs endothelial dystrophy, pseudophakic bullous keratopathy, aphakic bullous keratopathy, failed graft or iridocorneal endothelial syndrome.Study found that The DSAEK surgery enabled rapid and better UCVA and BSCVA when compared with PK, DLEK, and DSEK, with significantly lower astigmatism. Endothelial cell loss was similar, but the dislocation rate was significantly higher in the DSAEK group.

Borderie VM et al [30] studied and compared deep anterior lamellar keratoplasty (DALK) with penetrating keratoplasty (PK) in eyes with corneal diseases not involving the corneal endothelium (keratoconus, scars after infectious keratitis, stromal dystrophies, and trauma).One hundred forty-two consecutive DALK (DALK group; big-bubble technique or manual lamellar dissection using a slit lamp) and 142 matched PK (PK group).According to the study long-term, model-predicted graft survival and endothelial densities are higher after DALK than after PK. Compared with PK, manual dissection provides higher survival of both the corneal endothelium and graft, but lower visual acuity.

Liu M et al [31] studied to review the risk factors and pathogenesis of endothelial decompensation after penetrating keratoplasty (PKP) and its novel therapeutic strategies. According to this study any direct or indirect damage to the endothelium could cause the loss, morphological changes, and dysfunction of endothelial cells. Graft size, indica-

tions, and recipient glaucoma or glaucoma surgery history are risk factors for endothelial decompensation. DSAEK and DMEK are novel therapeutic strategies for failed PKP grafts and have potential superiorities compared with repeat PKP.

Cheng J et al [32] studied and compared the therapeutic effects of penetrating keratoplasty (PK) and deep anterior lamellar keratoplasty (DALK) on patients with macular corneal dystrophy (MCD) and to analyze the risk factors of postoperative recurrence. Fifty-one patients (78 eyes) with MCD treated by PK or DALK at Shandong Eye Institute between January 1992 and December 2010.According to this study, Penetrating keratoplasty more often immediately improves the visual acuity of patients with MCD, but many complications seem to be inevitable, especially continuous loss of corneal endothelium. Despite poor visual acuity and recurrence after surgery, DALK may produce fewer complications overall and more durable stability of the ocular surface compared with PK.

A Vong et al [33] studied and measured long term endothelial cell loss (ECC) following penetrating keratoplasty (PKP) for keratoconus (KCN). ECC was measured in eyes that had PKP from 1994-2008 for KCN. Only eyes with clear grafts were analyzed. ECC was compared to the original donor ECC. This study concluded that here is continuing long-term ECC loss years after PKP with the greatest loss in the first 5 years following surgery. Corneal clarity and visual acuity were not affected. Compliant patients without complicating factors had best corrected vision of 20/40 or better. Cataract surgery, refractive surgery, and resolved rejection episodes also led to continued endothelial cell loss but did not affect corneal clarity.

MATERIALS AND METHODS

Place of study

This retroprospective observational study consists of 32 subjects with history of keratoplasty who visited outpatient department at Department of Ophthalmology, Dayanand Medical College and Hospital, Ludhiana, Punjab (India). Prior approval from the Institutional Review Board was taken informed consent was taken from each subject. This study was conducted in accordance with the tenets of the Declaration of Helsinki for research involving human subjects.

METHOD OF COLLECTION OF DATA

Two groups were formulated.

GROUP A comprising of Full thickness corneal transplant patients

GROUP B comprising of Posterior lamellar corneal transplant patients

INCLUSION CRITERIA

Patients who had undergone full thickness keratoplasty from January 2019 to December 2020 were included in the study.

EXCLUSION CRITERIA

Graft with persistent epithelial defect significant scarring and interface haze in graft, not permitting Specular microscopy.

Ophthalmology examination including a complete history, slit lamp examination, specular microscopy was done. Noncontact specular microscopy (CEM-530 NIDEK) was performed, using an autofocus device, to assess the corneal endothelial status, and the endothelium visualized on an incorporated screen. Automated method was tried first, If not successful then we tried manual technique. The centres of contiguous cells were marked, after which the computer calculated and displayed the endothelial cell density (cells/mm^2) and analysed the number of cells. Specular microscopy was done at 1 year post keratoplasty.

Surgical technique for Posterior Lamellar Keratoplasty

For DSEK, Donor was prepared first followed by trephination of recipient tissue. In all the posterior lamellar keratoplasty cases, donor tissue was dissected manually. For manual disssection, donor button was taken on an artificial chamber and after inflating artificial chamber with air, tissue was dissected at approximately 90% stromal depth. Then, dissected donor tissue was transferred to a punching system and cut with required diameter trephine.

Under local anesthesia, surgery on recipient cornea was performed. Marking of the epithelium was done using sterile marker and temporal incision of 5mm was made incision may be clear corneal or scleral tunnel depending upon the individual case. By using reverse sinskey, scoring of the descement membrane was done. After stripping off the descement membrane and endothelium completely, donor cornea was brought into the operative field. Using sheet glide technique, donor tissue was inserted into the eye. Air was injected into the anterior chamber to promote donor tissue adherence. Temporal side port was sutured using one or two 10-0 monofilament sutures depending upon the individual case.

Surgical technique for Full Thickness Keratoplasty

After insertion of lid speculum, marking of the host cornea was done. Trephine size depend upon several factors, including host cornea size and pathology. After trephination donor cornea and host cornea after putting viscoelastic over the cornea. Recipient site was prepared using beveled corneal scissors. After removing the host cornea completely, anterior chamber was filled with viscoelastic. Then, donor corneal tissue was placed over the recipient site and four cardinal cardinal sutures were taken using 10-0 monofilament suture. Rest of the sutures taken and knots were buried.

OBSERVATIONS & RESULTS

Excluded patients

Of the total transplants done from January 2019 to December 2020,30 patients were not available for follow up possibly due to covid-19 pandemic and nineteen patients (35%) had failed graft.

Specular microscopy of four patients (7%) could not be captured because of interface haze. Two patient with graft perforation were also excluded.(Table1, Figure1)

Table1: Excluded Patients

Lost to follow up	30
Failed graft	19
Could not be captured	4
Graft perforation	2

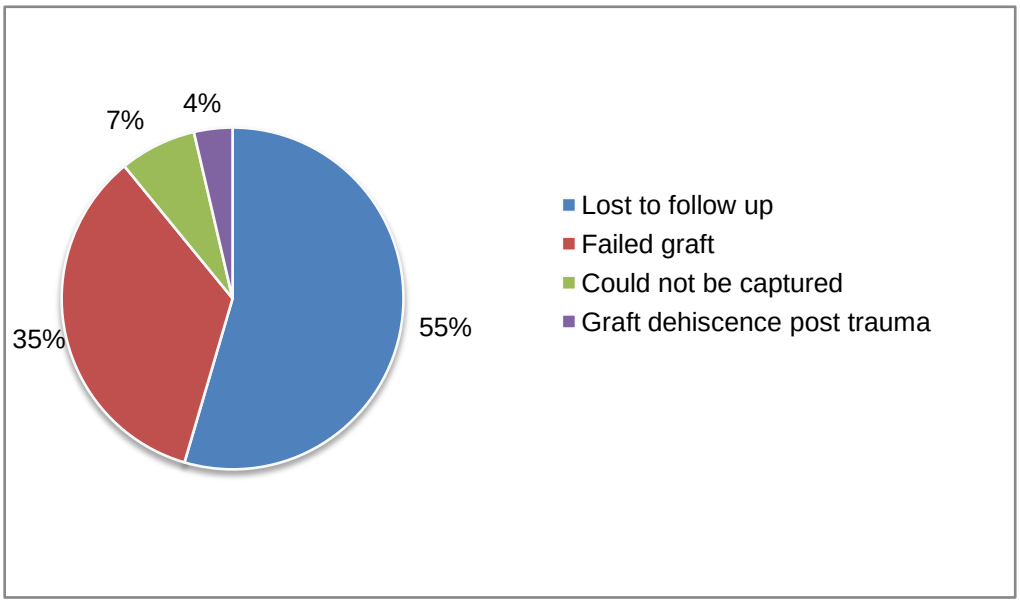

Figure 1: Excluded patient

Distribution of Patients

Table 2: Distribution of Patients

Keratoplasty	No. Of Patients	Percentage
Posterior Lamellar Keratop-lasty	18	56%
Full Thickness Keratoplasty	14	44%
Total	32	100%

Eighteen patients had undergone posterior lamellar keratoplasty (56% of 32 patients) and rest fourteen patients had history of full thickness keratoplasty (44% of 32 patients).

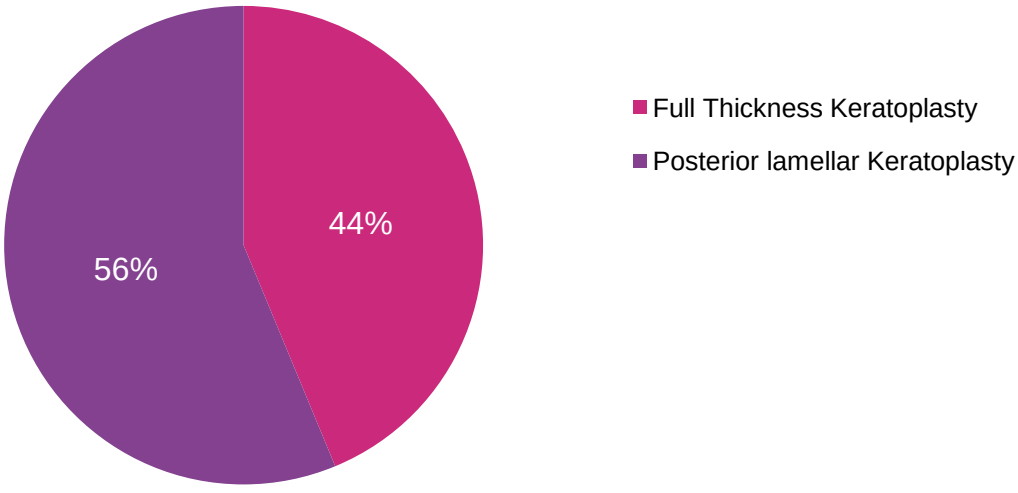

Figure: 2 Distribution of Patients

Age Distribution

Table 3: Age Distribution

	Posterior Lamellar Keratoplasty		Full Thickness Keratoplasty		
	Mean	Standard Deviation	Mean	Standard Deviation	P value
Age	62.00	6.95	50.50	15.46	0.013

The mean age of the patients with history of Posterior lamellar keratoplasty was 62.00±6.95 years with a range of 45 to 72 years .The mean age of patients who had undergone full thickness keratoplasty was 50.50 ± 15.46 years with range of 20 to 78 years. The difference in age in both the groups was statistically significant (p value = 0.007). (Table 3, Figure 3)

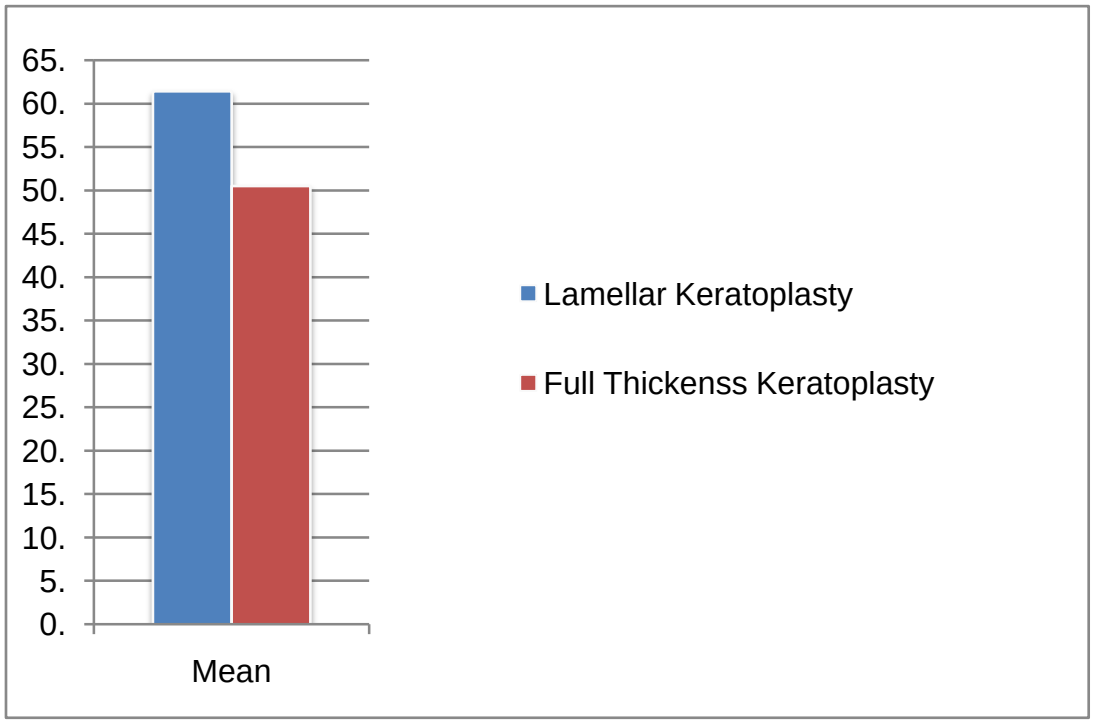

Figure 3: Age Distribution

Gender Distribution

Table 4: Gender distribution

Gender	Lamellar posterior Keratoplasty	Full Thickness Keratoplasty	Total
Male	15 (79%)	11 (79%)	26 (79%)
Female	3 (17%)	3 (21%)	6(21%)

The total number of male patients included in study was 26 (79%) and total number of female patients 6 (21%).In lamellar keratoplasty group, there were 15 males (79%) and 3 females (21%).In full thickness keratoplasty group there were 11 males (79%) and 3 males (21%).

(Table 4, Figure 4)

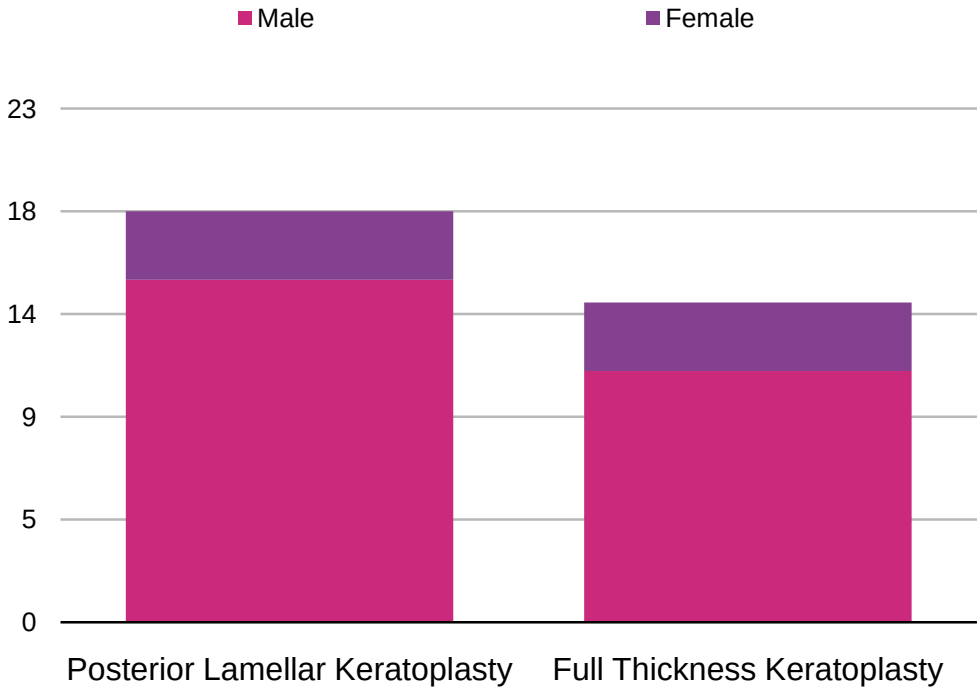

Figure 4: Gender distribution

Surgical Indications

Table:5 Surgical Indications in Posterior Lamellar keratoplasty

Indication	Posterior Lamellar Keratoplasty
Pseudophakic bullouskeratopathy	13
Aphakic bullous keratopathy	1
Phakic corneal edema	1
Failed graft	3
Total	18

For posterior lamellar keratoplasty, Pseudophakic bullous keratopathy (72%) was the most common indication followed by failed graft in 15% of the cases (Table 5, Figure 5)

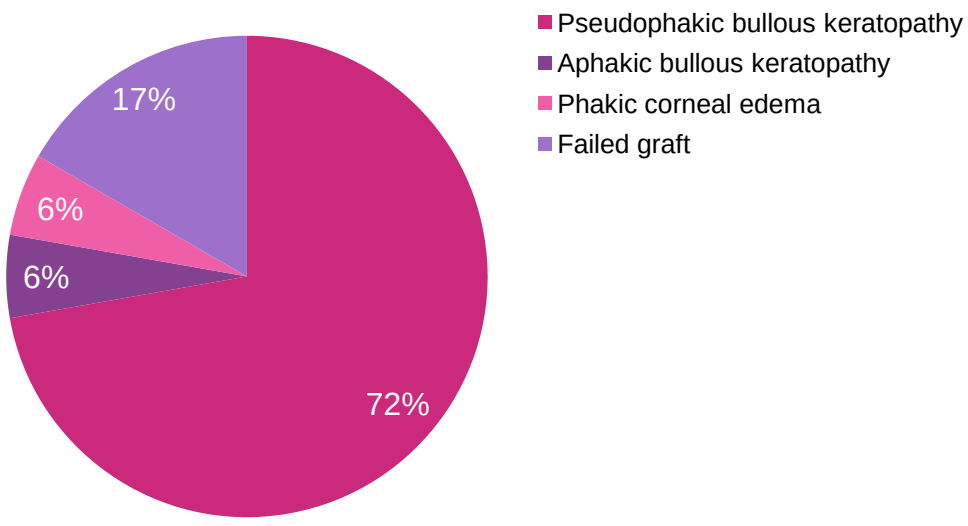

Figure 5: Surgical Indications in Posterior Lamellar Keratoplasty

Table: 6 Surgical Indications in Full Thickness Keratoplasty

Indication	Full thickness keratoplasty
Advanced corneal ulcer	2
Failed graft	2
Healed viral keratitis	3
Perforated corneal ulcer	6
Total	13

In cases of full thickness keratoplasty, Perforated corneal ulcer (46%) is the most common indication and others were advanced corneal ulcer (15%), healed viral keratitis (23%) and failed graft in (15%) of the cases.(Table 6, Figure 6)

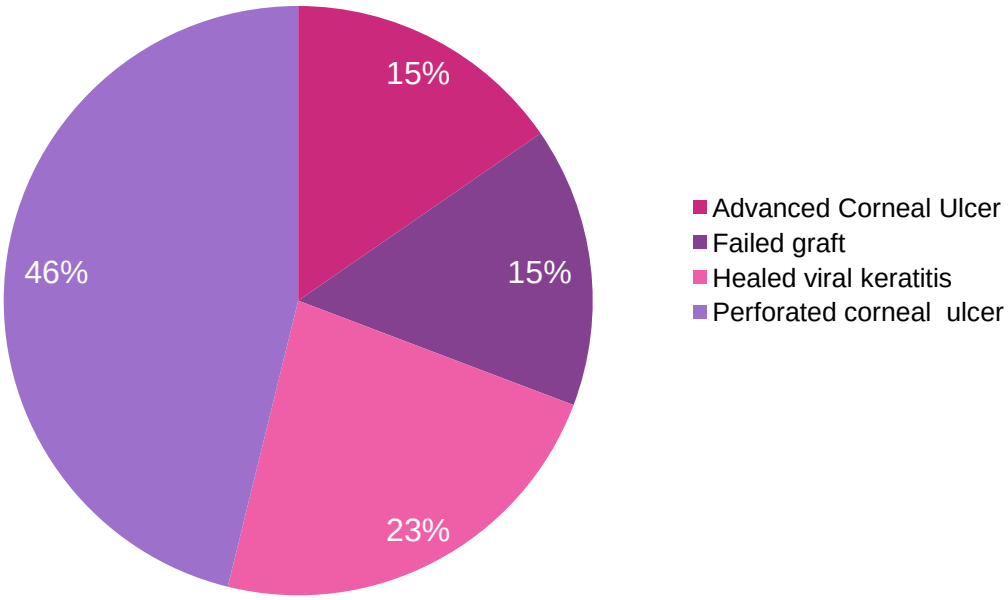

Figure 6: Surgical Indications in Full Thickness Keratoplasty

Table 7: Mean Best Corrected Visual Acuity In Posterior Lamellar Keratoplasty

	Mean	Standard Deviation
Baseline BCVA	1.50	0.20
BCVA at 12 months	0.47	0.34

In posterior lamellar keratoplasty group, the mean logMAR BCVA at baseline was 1.50±0.20 logMAR and 0.47±0.34 logMAR at 12 months.
(Table 7, Figure 7)

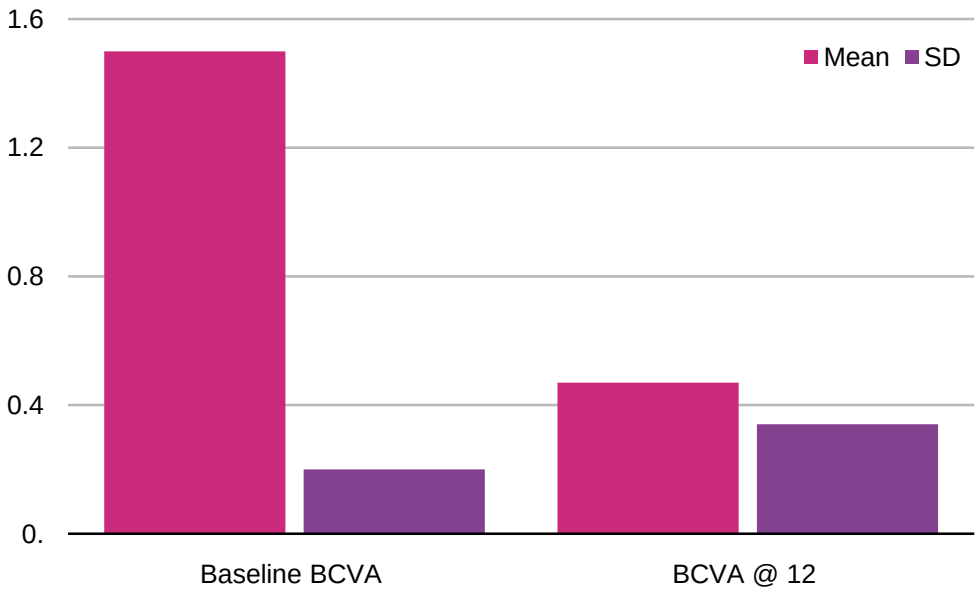

Figure 7: Mean Best Corrected Visual Acuity In Posterior Lamellar Keratoplasty

Table 8: Mean Best Corrected Visual Acuity In Full thickness Keratoplasty

	Full Thickness Keratoplasty	
	Mean	Standard Deviation
Baseline BCVA	1.69	0.15
BCVA at 12 months	0.44	0.32

In full thickness keratoplasty group, the mean logMAR BCVA at baseline was 1.69±0.15 logMAR and 0.44±0.32 logMAR at 12 months. (Table 8, Figure 8)

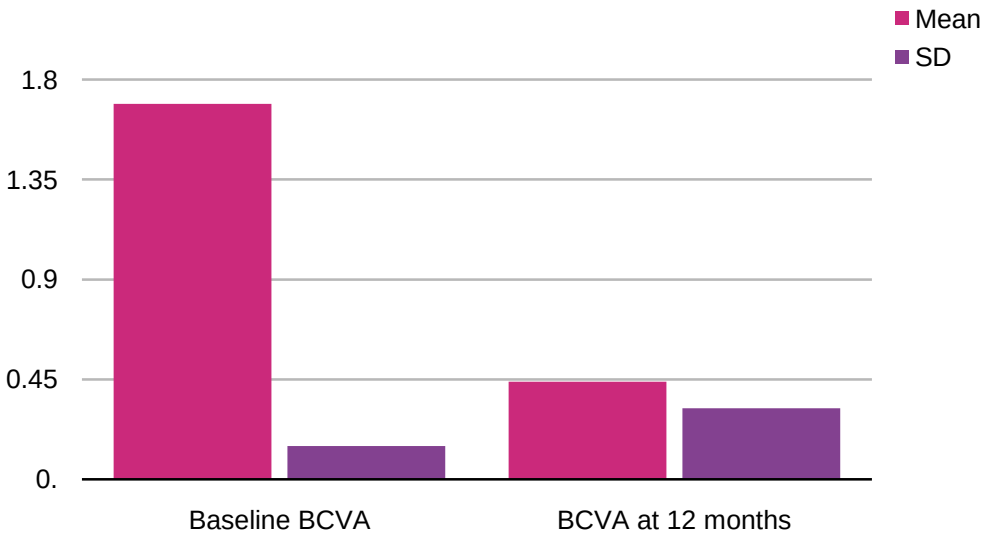

Figure 8: Mean Best Corrected Visual Acuity In full Thickness Keratoplasty

Endothelial Cell Density

Table 9: Endothelial Cell Density

	Posterior Lamellar Keratoplasty		Full Thickness Kera-toplasty		
	Mean	Standard Deviation	Mean	Standard Deviation	P value
Baseline ECD	2871.68	161.69	2857.43	257.71	0.466
ECD 12 Month	1737.89	557.72	1744.00	570.53	0.776

Preoperative mean ECD of the donor corneas used for the posterior lamellar keratoplasty group was 2871±161.69 cells/mm$^{2.}$ Preoperative mean ECD of the donor corneas used for the full thickness keratop-lasty group was 2857±257.71 cells/mm^2.

Mean endothelial cell density at 12 months in posterior lamellar kera-toplasty group was 1737±557.72cells/mm^{2}Mean ECD at 12 months in full thickness keratoplasty group is found to be 1744±570.53 cells/mm^{2}Difference in ECD at 12 months was not found be significant statistically (Table 9, Figure 9).

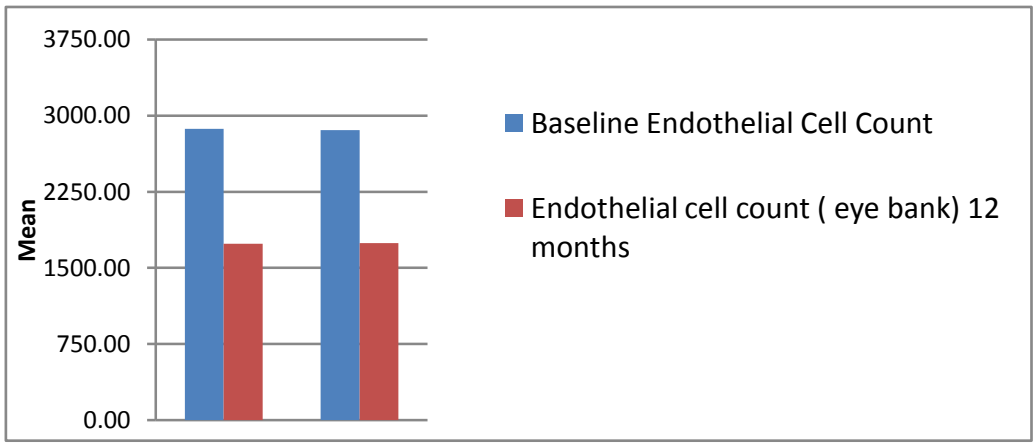

Figure 9: Endothelial Cell Density

Percentage Cell Loss at 12 months Post Keratoplasty

Table 10: Percentage Cell Loss at 12 months Post Keratoplasty

	Posterior Lamellar Keratoplasty		Full Thickness Keratoplasty		
	Mean	Standard Deviation	Mean	Standard Deviation	P value
Percentage Cell loss at 12 year	39.55	18.96	38.69	19.90	0.716

The mean endothelial cell loss at 12 months in posterior lamellar keratoplasty is 39.55±18.96 % and 38.69±19.90% in patients with full thickness keratoplasty. Difference was not found to be significant. (Table 10, Figure 10).

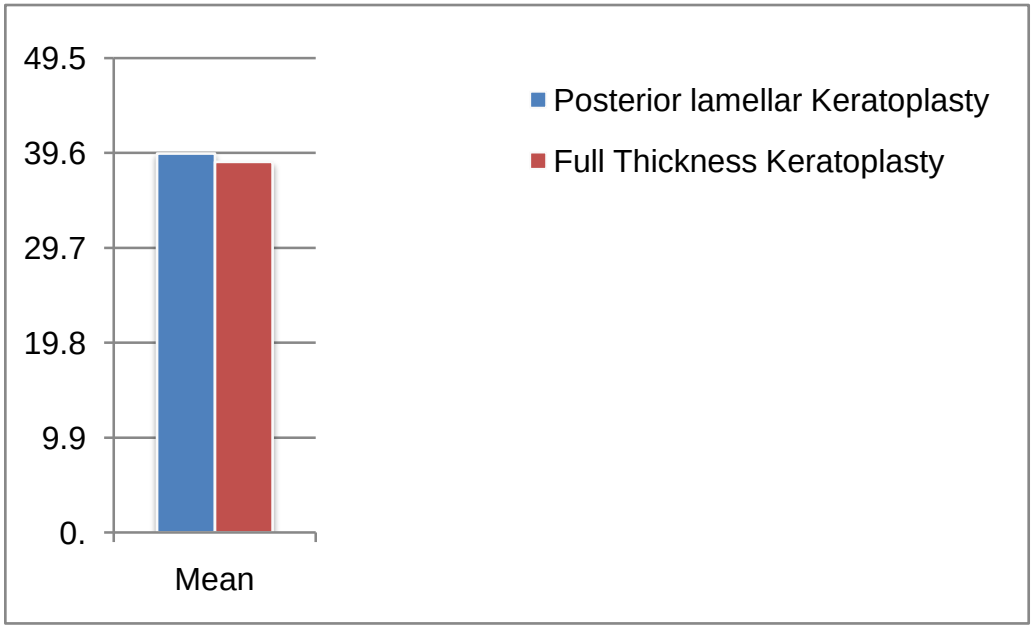

Figure10 Percentage Cell Loss at 12 months Post Keratoplasty

DISCUSSION

Our main interest in this study was to find the ECD at one year in the above mentioned keratoplasty procedures. The main goal of transplant in Pseudophakic bullous keratopathy and Fuchs endothelial dystrophy patients is to replace the diseased endothelium with healthy, viable endothelial cells to restore the transparency of the cornea. Refractive issues like irregular astigmatism and high spherical refractive errors are well known in penetrating keratoplasty cases. Ultimately, in these cases, glasses and contact lens are required. Some patients often cannot tolerate contact lenses and glasses. In extreme cases, repeat full thickness keratoplasty may be required to manage the astigmatism. Graft rejection, graft dehiscence, suture -related problems and surface issues are common in post PKP patients. Therefore with posterior lamellar keratoplasty, many of these sight threatening complications related to PKP can be avoided. As only 1 or 2 sutures are placed in posterior lamellar keratoplasty, therefore long-term suture related complications are avoided. Acute endothelial rejection may occur in patients undergoing PKP or posterior lamellar keratoplasty. Furthermore, onset of acute allograft rejection and subsequent treatment varies greatly between cases.

Patient characteristics and ophthalmic problems may have been different in each group. We tried to minimize differences in the posterior lamellar and full thickness groups by including patients undergoing PK with the best prognosis. We excluded the graft rejection cases to minimize variation in two groups. Other patients with complications like infections and post-trauma graft dehiscence were not included in this study to reduce bias but loss to follow up cases were high due to ongoing covid pandemic. All tests were performed by the same technician in the same office, by using the same equipment during the same period.

Various previous studies have documented the benefits of posterior lamellar keratoplasty over PKP. Price MO et al[26] concluded that the

most significant advantages of DSEK over PKP are that the recipient cornea remains structurally intact and is more resistant to injury. The principal advantages of DSEK over PLK or DLEK are that no complex recipient dissection and trephination techniques are required and there is less potential for trauma to the anterior chamber and lens.

Direct comparisons with PKP and posterior lamellar keratoplasty are difficult because of unknown variables such as demographics, techniques and instrumentations used. In this study we compared 18 posterior lamellar keraoplasty cases with 14 PKP cases. These surgeries were operated by same surgeon during the same period. Endothelial cells are responsible for graft survival in any kind of keratoplasty. The normal ECD declines with age**.** Bo-I-Ku et al [20]studied and compared endothelial cell density (ECD) loss rates in penetrating keratoplasty (PKP), Descemet's stripping automated endothelial keratoplasty (DSAEK), and deep anterior lamellar keratoplasty (DALK) and found that the normal corneal ECD declines with age and the physiologic loss is approximately 0.6% per year.PKP has been shown to have acclerated cell loss of with rate of 28% after 6 months and 39.8% after 12 months in a study conducted by Jonathan H .Lass et al[26] There were various contributing factors like surgical trauma, ageing, secondary glaucoma and donor preservation conditions as stated by Kubaloglu A et al [25].

Although DSEK is associated with fewer imnune reactions due to smaller surgical wound as stated earlier, but due to vigrous manipulation of the graft intraoperatively in DSEK , there might be higher endothelial cell loss density in immediate post operative period. The average ECD loss percentage in both PKP and DSEK groups (PKP vs. DSEK: 28%–32% vs. 20%–35.8%) at one year [34-38]. Price *et al* [39] concluded that that DSEK had a substantially high, ECD loss rate within the 1styear. On the contrary, Ang et al [22] showed that DSAEK resulted in lower endothelial cell loss for up to 1 year in patients with Fuch' dystrophy and bullous keratopathy. In our study, mean percen-

tage cell loss at 12 months in lamellar keratoplasty is 39.55±18.96% and 38.69±19.91% in patients with full thickness keratoplasty. In DSEK group, ECD loss is higher than various published studies. More intraoperative manipulation can explain this trend. We did not measure the ECD of donors after preparation of DSEK grafts, which could cause more ECD loss and explained the DSEK group had a substantially high ECD loss rate in the early postoperative period. In present study, there were 18 patients in posterior lamellar keratoplasty group as compared to PKP which has only 14 patients. These PKP patients are those which has best success rate at 1 year. Due to covid pandemic, patients did not turn up as expected. Our results of the ECD loss rate were also consistent with other studies [22, 26] that focused on the loss percentage of ECD. Therefore, we were in agreement in that DSAEK had more endothelial cell loss than PKP at 1 year.

William M Bourne et al [2] asked the recipients of 500 consecutive corneal transplants to return for examination and endothelial photography at two months and at one, three, and five years postoperatively. They also recorded episodes of graft rejection and failure. In 129 grafts in patients who returned at each postoperative interval and had no rejection episodes, the mean endothelial cell density continued to decrease 7.8% per year from three years to five years after keratoplasty, compared with approximately 0.5% per year in unoperated- on normal corneas. The mean cell loss compared with the preoperative examination was 58.9% five years after keratoplasty. The percentage of hexagonal cells did not return to preoperative levels by five years after keratoplasty, suggesting that the endothelîum continued to be unstable. The mean corneal thickness increased significantly with time. Low endothelial cell densities were statistically significantly associated with increased corneal thickness and with an increased risk of subsequent failure.

Although Posterior lamellar keratoplasty is associated with less immune reaction, less number of sutures and moreover, intact surface

that makes antigen presenting cells difficult to access the graft. However, due to vigorous manipulation of the endothelial graft during the surgery, DSEK is known to have tremendous endothelial cell loss and might result in primary graft failure. Bo-I-Ku et al [20] studied and compared endothelial cell density (ECD) loss rates in penetrating keratoplasty (PKP), Descemet's stripping automated endothelial keratoplasty (DSAEK), and deep anterior lamellar keratoplasty (DALK) and found that the normal corneal ECD declines with age and the physiologic loss is approximately 0.6% per year.

Table 11: Comparison of Average Endothelial Cell Loss In Posterior

Study	Technique used in Posterior Lamellar Keratoplasty	ECD loss in Posterior Lamellar Keratoplasty	ECD loss in Full Thickness Keratoplasty
Present study	Sheet glide push in technique	39.55%	38.69%
Ang et al[22]	Sheet glide pull in	29.5%	36.5%
Price MO et al[26]	Funnel glide	38%	23%
Ishiyama et al [35]	N/A	37.21%	32.05%
Bo-I Ku et al [20]	N/A	45%	31.1%
Bahar et al [29]	Taco folding	38.2%	39.6%
Van Dooren et al [21]	Busin glide	56%	24%

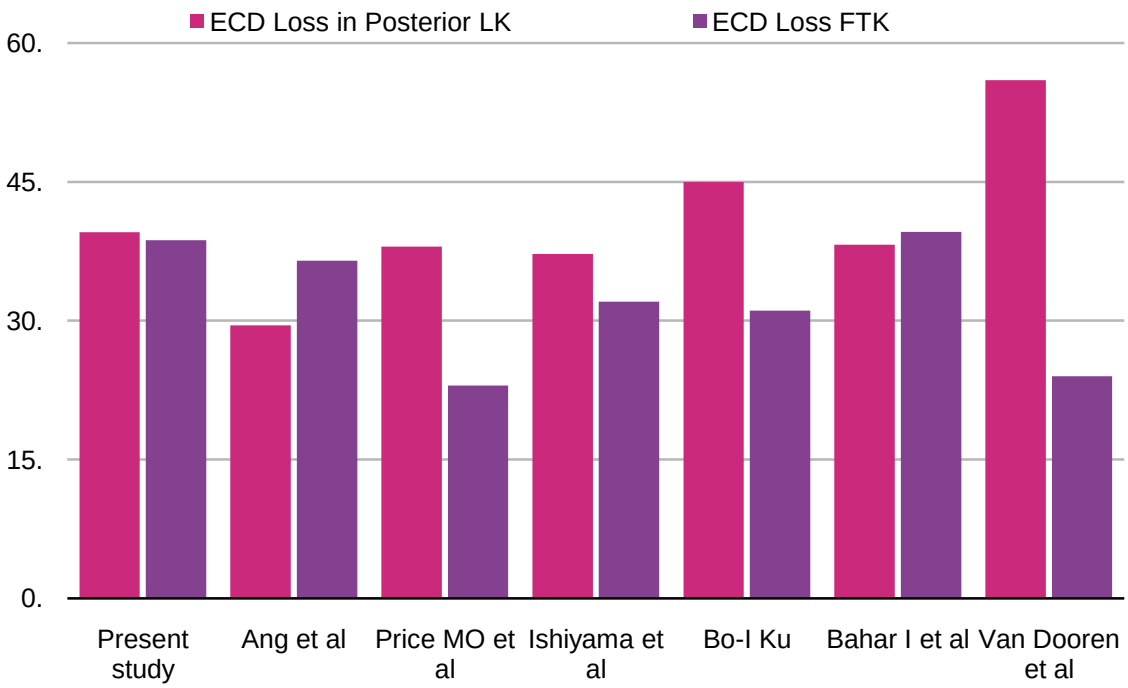

Figure 11 Comparison of Average Endothelial Cell Loss In Posterior Lamellar Keratoplasty and Full Thickness Keratoplasty at 12 Months

SUMMARY AND CONCLUSION

As per previous studies discussed in present study, It is clear and evident that loss in endothelial cell density is more in lamellar keratoplasty at 1 year as compared to full thickness keratoplasty.

Limitations of this study includes high attrition and small number of cases that might be due to ongoing covid pandemic.

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Sr no	MRD no.	Age	Sex	Occupation	Indication	Chief complaints	History of corneal transplant	Right BCVA	Left BCVA	conjunctiva
1	498047	55y	M	Farmer	Pseudophakic bullous keratopathy	Watering	5-1-2019	6-60	6-6	Normal
2	555130	65y	M	Farmer	Pseudophakic bullous keratopathy	No	9-5-2021	6-36	6-24	normal
3	649457	59y	M	Doctor	Failed graft	Blurring of vision	10-5-2019	6-9	6-6	pterygium
4	649457	58y	M	Doctor	Failed graft	No	12-1-19	6-9	6-6	Normal
5	631195	57y	M	Daily wager	Healed keratitis	No	20-6-2019	6-6	3-60	Normal
6	753713	63y	M	Shopkeeper	Pseudophakic bullous keratopathy	No	11-7-2019	6-9	6-9	Normal
7	555130	68y	M	Farmer	Pseudophakic bullous keratopathy	Foreign body sensation	11-7-2019	6-36	6-24	Foreign body
8	555130	68y	M	Farmer	Pseudophakic bullous keratopathy	No	2-8-19	6-36	6-24	Normal
9	743786	71y	M	Farmer	Phakic corneal edema	Blurring of vision	19-9-2019	6-60	6-18	normal
10	792352	64y	M	Labourer	Pseudophakic bullous keratopathy	No	11-9-2019	6-9	6-6	Normal
11	822417	72y	F	Homemaker	Pseudophakic bullous keratopathy	blurring of vision	16-10-2019	6-60	Finger count at half metre	Normal
12	856679	46y	M	Shopkeeper	Perforated corneal ulcer	no	6-12-2019	6-18	6-6	Normal
13	858222	52y	M	Farmer	Perforated corneal ulcer	Mild foreign body sensation	10-12-2019	6-6	6-9	Normal
14	609458	28y	M	Daily wager	Failed graft	No	23-1-20	6-6	6-9	Normal
15	623549	20y	M	Student	Perforated corneal ulcer	Blurring of vision	13-3-2020	6-6	9-21	Normal
16	515543	57y	M	labourer	Perforated corneal ulcer	No	12-3-2020	6-12	6-9	Normal
17	631195	55y	M	Labourer	Advanced corneal ulcer	Blurring of vision	20-6-2020	6-6	6-18	Normal
18	39439	78y	M	Farmer	Healed keratitis	no	5-2-2020	No PL	FC at 1 m	Normal
19	885262	61y	F	Homemaker	Aphakic bullous keratopathy	No	10-2-2020	6-6	6-12	Normal
20	79315	51y	F	Homemaker	Pseudophakic bullous keratopathy	No	25-6-2020	-	-	-
21	599872	52y	M	Govt employee	Failed graft	No	7-8-2020	6-9	6-6	Normal
22	932056	63y	F	Homemaker	Pseudophakic bullous keratopathy	No	1-7-2020	6-6	6-18	Normal
23	814368	61y	F	Homemaker	Perforated corneal ulcer	No	20-9-2019	Fc at 2m	6-24	Normal
24	432172	53y	M	Shopkeeper	Pseudophakic bullous keratopathy	No	20-11-2020	6-18	PL negative	Normal
25	682854	65y	M	Shopkeeper	Perforated corneal ulcer	Whitish discolouration	5-3-2019	Fc at 2m	6-36	Normal
26	976959	70y	M	Govt employee	Pseudophakic bullous keratopathy	-	3-12-2020	6-9	6-18	Normal
27	788719	60y	M	Daily wager	Failed graft	Blurring of vision	29-10-2020	No PL	6-12	Normal
28	331241	30Y	F	Student	Perforated corneal ulcer	Blurring of vision	09-11-2019	6-9	6-18	Normal
29	528621	54y	M	Farmer	Healed keratitis	No	5-6-2019	6-12	6-6	Normal
30	812734	50y	F	Homemaker	Advanced corneal ulcer	no	2-3-2019	6-12	6-36	Normal
31	668911	65y	M	Teacher	Pseudophakic bullous keratopathy	Watering	24-8-2019	6-24	6-6	Normal
32	5520232	-	M	-	Left eye failed graft	Diminution of vision	10-4-2019	-	-	-
33	560648	54y	F	-	Corneal scar	Blurring of vision	9-5-2019	-	-	-
34	734945	40y	M	-	Perforated corneal ulcer	-	27-5-2019	-	-	-
35	574390	70y	M	-	Vascularised corneal scar	-	5-6-2019	-	-	-
36	731808	38y	F	-	-	-	6-6-2019	-	-	-
37	733522	80y	F	-	Pseudophakic bullous keratopathy	Blurring of vision	7-6-2019	-	-	-
38	696425	82 y	M	-	Pseudophakic bullous keratopathy	-	13-6-2019	-	-	-
39	747545	75y	F	-	Left eye healed keratitis	-	19-6-2019	-	-	-
40	749878	-	-	-	Perforated corneal ulcer	-	27-6-2021	-	-	-
41	760699	58y	M	-	Advanced fungal corneal ulcer	-	4-7-2019	-	-	-
42	54245	-	F	-	Pseudophakic bullous keratopathy	-	10-7-2019	-	-	-
43	770486	-	M	-	Pseudophakic bullous keratopathy	-	1-8-2019	-	-	-
44	615937	58y	M	-	S/p CTR , aphakia	-	7-8-2019	-	-	-
45	797768	80y	M	-	Perforated corneal ulcer	-	29-8-2019	-	-	-
46	792037	47y	M	-	-	-	29-7-2020	-	-	-
47	36206	-	M	-	Healed viral keratitis	-	13-9-2019	-	-	-
48	812734	50y	F	-	Pseudophakic bullous keratopathy	-	19-9-2019	-	-	-
49	811312	65y	F	-	Pseudophakic bullous keratopathy	-	19-9-2019	-	-	-
50	668911	-	M	-	Pseudophakic bullous keratopathy	-	24-9-2019	-	-	-
51	819515	37y	M	-	Perforated corneal ulcer	-	28-9-2019	-	-	-
53	571767	45y	M	Shopkeeper	Pseudophakic bullous keratopathy	-	18-10-2019	6-18	6-9	Normal
54	85957	33Y	M	-	Perforated corneal ulcer	-	19-12-2019	-	-	-
55	871514	61y	M	-	Pseudophakic bullous keratopathy	-	26-12-2019	-	-	-
56	852426	35y	F	-	Perforated corneal ulcer	-	30-12-2019	-	-	-
58	423077	59y	M	Labourer	Healed keratitis	-	31-12-2019	6-18	6-6	Normal
59	675527	41y	F	-	Corneal fistula	-	21-1-2020	-	-	-

Sr no	MRD no.	Ocular examination					Baseline Endothelial Cell Count	Endothelial cell count in		Parameters at 12 months			Comments
		cornea	anterior chamber	pupils	lens	GAT		Lamellar keratoplasty	Full Thickness Keratoplasty	Endothelial cell density	Coefficient of variation	Hexagonality	
1	498047	Lenticular attached	Quiet	Reactive	pseudophakia	14	3080	60	-	2410	34	47	-
2	555130	Lenticule attached	Quiet	reactive	pseudophakia	16	2800	35	-	837	41	46	-
3	649457	clear	quiet	reactive	pseudophakia	12	3250	126	-	1807	41	34	-
4	649457	clear	Quiet	reactive	pseudophakia	13	2980	96	-	2155	39	33	-
5	631195	clear	Quiet	reactive	pseudophakia	16	2650	119	-	2065	21	158	-
6	753713	clear	Quiet	reactive	pseudophakia	12	2850	69	-	1040	13	71	-
7	555130	clear	Quiet	reactive	pseudophakia	10	2934	836	-	1194	41	46	-
8	555130	clear	quiet	reactive	pseudophakia	18	2835	747	-	1339	62	46	-
9	743786	clear	quiet	reactive	pseudophakia	14	2810	399	-	2504	38	31	-
10	792352	clear	quiet	reactive	pseudophakia	22	2865	25	-	2037	26	32	-
11	822417	Lenticular attached	quiet	reactive	pseudophakia	10	2970	106	-	2848	44	49	-
12	856679	Sutures in situ	quiet	reactive	pseudophakia	18	2984	-	52	2233	37	62	-
13	858222	Sutures in situ	quiet	reactive	pseudophakia	18	2854	-	87	2540	36	70	-
14	609458	clear	quiet	reactive	Immature cataract	12	2050	-	785	1274	69	32	-
15	623549	clear	quiet	reactive	PSC	20	2660	-	101	2456	42	52	-
16	515543	clear	quiet	reactive	clear	12	2860	-	76	1557	37	43	-
17	631195	clear	quiet	reactive	pseudophakia	16	3012	-	119	2065	21	75	-
18	39439	clear	quiet	reactive	pseudophakia	14	2890	-	122	1960	29	39	-
19	885262	clear	quiet	reactive	pseudophakia	10	2874	80	-	1943	35	30	-
20	79315	-	-	-	-	-	-	-	-	-	-	-	Failed graft
21	599872	clear	quiet	reactive	pseudophakia	12	3044	-	53	1095	52	27	-
22	932056	clear	quiet	reactive	pseudophakia	10	2982	78	-	1374	49	27	-
23	814368	clear	quiet	reactive	pseudophakia	18	3026	-	42	941	34	43	-
24	432172	clear	quiet	reactive	pseudophakia	12	2694	68	-	2132	43	40	-
25	682854	Hazy	quiet	reactive	pseudophakia	14	2809	-	56	904	32	41	-
26	976959	clear	quiet	reactive	pseudophakia	16	3035	50	-	1665	38	32	-
27	788719	Lenticular attached	quiet	reactive	pseudophakia	22	2670	59	-	1256	47	30	-
28	331241	clear	quiet	reactive	PSC	10	3028	-	154	2258	91	34	-
29	528621	clear	quiet	reactive	pseudophakia	12	2840	-	73	1452	47	38	-
30	812734	clear	quiet	reactive	pseudophakia	14	3027	-	66	1449	35	41	-
31	668911	clear	quiet	reactive	pseudophakia	16	2760	54	-	1360	43	48	-
32	5520232	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
33	560648	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
34	734945	-	-	-	-	-	-	-	-	-	-	-	Failed graft
35	574390	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
36	731808	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
37	733522	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
38	696425	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
39	747545	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
40	749878	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
41	760699	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
42	54245	-	-	-	-	-	-	-	-	-	-	-	Failed graft
43	770486	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
44	615937	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
45	797768	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
46	792037	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
47	36206	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
48	812734	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
49	811312	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
50	668911	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
51	819515	-	-	-	-	-	-	-	-	-	-	-	Failed graft
53	571767	Nasal quadrant corneal edema	quiet	reactive	pseudophakia	12	2650	48	-	1316	43	36	-
54	85957	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
55	871514	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
56	852426	-	-	-	-	-	-	-	-	-	-	-	Failed graft
58	423077	clear	quiet	reactive	pseudophakia	20	2920	-	157	2232	26	66	-
59	675527	-	-	-	-	-	-	-	-	-	-	-	Failed graft

Sr no	MRD no.	Age	Sex	Occupation	Indication	Chief complaints	History of corneal transplant	Right BCVA	Left BCVA	conjunctiva
60	880480	70y	F	-	Pseudophakic bullous keratopathy	-	23-1-2020	-	-	-
61	884621	72y	F	-	Pseudophakic bullous keratopathy	-	13-2-2020	-	-	-
62	981452	60y	F	-	Fuchs endothelial dystrophy	-	12-3-2020	-	-	-
63	914896	77y	F	-	Pseudophakic bullous keratopathy	-	12-3-2020	-	-	-
64	448353	71y	M	-	Perforated corneal ulcer	-	19-3-2020	-	-	-
65	923979	38y	M	-	Perforated corneal ulcer	-	28-4-2020	-	-	-
66	923710	50y	M	-	Perforated corneal ulcer	-	4-5-2020	-	-	-
67	927455	46y	M	-	Sterile melt sjs sequelae	-	18-5-2020	-	-	-
68	926361	48y	M	-	Perforated corneal ulcer	-	23-5-2020	-	-	-
69	937146	-	M	-	Perforated corneal ulcer	-	25-6-2020	-	-	-
70	942289	30y	M	-	Perforated corneal ulcer	-	17-7-2020	-	-	-
71	944649	65y	F	-	Pseudophakic bullous keratopathy	-	25-7-2020	-	-	-
72	899700	40y	M	-	Vascularised corneal scar	-	6-8-2020	-	-	-
73	949814	33y	M	-	Failed graft	-	6-8-2020	-	-	-
74	732965	44y	F	-	Failed graft	-	10-10-2020	-	-	-
75	774109	61y	M	-	Recurrent viral keratouveitis	-	12-10-2020	-	-	-
76	970469	28y	M	-	Acute keratitis	-	14-10-2020	-	-	-
77	930658	9 months	M	-	Perforated corneal ulcer	-	3-11-2020	-	-	-
78	969126	60y	F	-	Perforated corneal ulcer	-	19-11-2020	-	-	-
79	988956	76y	M	-	Sclerokeratitis	-	20-11-2020	-	-	-
80	772347	59y	F	-	Endophthalmitis	-	23-11-2020	-	-	-
81	954430	50y	M	-	Failed graft	-	30-11-2020	-	-	-
82	794564	61y	M	-	Pseudophakic bullous keratopathy	-	3-12-2020	-	-	-
83	973853	72y	M	-	PED	-	3-12-2020	-	-	-
84	977831	65y	F	-	Advanced corneal ulcer	-	4-12-2020	-	-	-
85	1003624	69y	M	-	Fuchs endothelial dystrophy	-	20-12-2020	-	-	-
86	1004153	65y	F	-	Pseudophakic bullous keratopathy	-	24-12-2020	-	-	-
87	998654	57y	M	-	Perforated corneal ulcer	-	24-12-2020	-	-	-

Sr no	MRD no.	Ocular examination					Baseline Endothelial Cell Count	Endothelial cell count in		Parameters at 12 months			Comments
		cornea	anterior chamber	pupils	lens	GAT		Lamellar keratoplasty	Full Thickness Keratoplasty	Endothelial cell density	Coefficient of variation	Hexagonality	
60	880480	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
61	884621	-	-	-	-	-	-	-	-	-	-	-	Could not be captured
62	981452	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
63	914896	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
64	448353	-	-	-	-	-	-	-	-	-	-	-	Failed graft
65	923979	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
66	923710	-	-	-	-	-	-	-	-	-	-	-	Failed graft
67	927455	-	-	-	-	-	-	-	-	-	-	-	Failed graft
68	926361	-	-	-	-	-	-	-	-	-	-	-	Failed graft
69	937146	-	-	-	-	-	-	-	-	-	-	-	Failed graft
70	942289	-	-	-	-	-	-	-	-	-	-	-	Failed graft
71	944649	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
72	899700	-	-	-	-	-	-	-	-	-	-	-	Graft perforation
73	949814	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
74	732965	-	-	-	-	-	-	-	-	-	-	-	Could not be captured
75	774109	-	-	-	-	-	-	-	-	-	-	-	Could not be captured
76	970469	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
77	930658	-	-	-	-	-	-	-	-	-	-	-	Could not be captured
78	969126	-	-	-	-	-	-	-	-	-	-	-	Failed graft
79	988956	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
80	772347	-	-	-	-	-	-	-	-	-	-	-	Graft perforation
81	954430	-	-	-	-	-	-	-	-	-	-	-	Failed graft
82	794564	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
83	973853	-	-	-	-	-	-	-	-	-	-	-	Failed graft
84	977831	-	-	-	-	-	-	-	-	-	-	-	Failed graft
85	1003624	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
86	1004153	-	-	-	-	-	-	-	-	-	-	-	Lost to follow up
87	998654	-	-	-	-	-	-	-	-	-	-	-	Failed graft

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DMC,Ludhiana.

Subject: **Approval of Plan of Thesis.**

This is to inform you that the Faculty of Medical Sciences in its meeting held on 22.01.2021 has approved the plan of thesis of **Dr. Chandandeep Kaur Gill,** a student of your college for **MS Ophthalmology** along with the names of Supervisor/Co-Supervisor as under:-

Topic Plan of Thesis
To compare endothelial cell count at 1 year between full thickness and lamellar corneal transplant

Supervisor
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Co-Supervisor
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The student has to submit the three copies of thesis (along with PDF format) , to the Controller of Examinations, BFUHS, Faridkot, at least six months before the commencement of theory examination, if he/she is otherwise eligible to take the examination. He /She must directed to attach a photocopy of this letter with the forwarding letter while submitting thesis to the University along with the letter of approval of University for change of supervisor/Co-Supervisor, change of topic,(if any).

Dr. S P Singh MS(Oph)
Controller of Examinations

Note :

1. ***If any discrepancy found regarding topic of thesis or Supervisor/Co-Supervisor, inform undersigned within one month after issue of this letter.***
2. *The student may submit the thesis as per the schedule already conveyed i.e for May/June examination 30th Nov of the preceding the year of examination and for Nov/Dec examinations 31st May of the year of examination.*

TO COMPARE ENDOTHELIAL CELL COUNT AT 1 YEAR BETWEEN FULL THICKNESS AND LAMELLAR CORNEAL TRANSPLANT

THESIS PROPOSAL

FOR APPROVAL OF SUBJECT OF THESIS TO BE SUBMITTED IN

PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE DEGREE OF

MS

In

Department of Ophthalmology

OF THE

BABA FARID UNIVERSITY OF HEALTH SCIENCES

FARIDKOT

November, 2019

Dr. Chandandeep Kaur Gill

DEPARTMENT OF OPHTHALMOLOGY
DAYANAND MEDICAL COLLEGE AND HOSPITAL
LUDHIANA

ABSTRACT OF PLAN OF THESIS

Title	To compare Endothelial cell count at 1 year between Full thickness and Lamellar corneal transplant
For the degree of	MS Ophthalmology
Name of the candidate	Dr. Chandandeep Kaur Gill
Supervisor	Dr. Sumeet Chopra, Professor and Head, Department of Ophthalmology, DMCH, Ludhiana
Co-supervisor	Dr. Priyanka Arora, Associate Professor, Department of Ophthalmology, DMCH, Ludhiana Dr. Sahil Goel, , Assistant Professor, Department of Ophthalmology, DMCH, Ludhiana
Institution	Dayanand Medical College & Hospital, Ludhiana
University	Baba Farid University of Health Sciences, Faridkot

Introduction:

Full Thickness corneal transplant has been the standard treatment option for corneal replacement for many years.It is an established procedure whereas Lamellar keratoplasty is relatively a newer procedure .Endothelial cell loss is common concern after corneal transplant of both full thickness and lamellar corneal transplant. Endothelial rejection can lead to endothelial cell damage and eventually, decrease the corneal transparency.

Aim of Study: To compare the endothelial cell count in patients at 1 year follow up after Full thickness and Lamellar Corneal Transplant.

Materials & methods: In this prospective study all patients with history of full thickness and lamellar corneal transplant presenting to the out patient services between january 2020 and june 2019 will be recruited .All the subjects will be subjected to detailed slit lamp examination and endothelial cell count uusing specular microscopy .Results will be compared between the two.

Clinical Significance: Corneal endothelium plays a major role in maintaining the optical transparency of the cornea.Thus, endothelial cell loss predicts the prognosis of corneal transplant.

Keywords: Full thickness corneal transplant, lamellar corneal transplant, corneal endothelium, specular microscopy

(Signature)	(Signature)	(Signature)	(Signature)	(Signature)
Candidate	Co-supervisor	Co-supervisor	Supervisor	Principal

CERTIFICATE OF FACILITIES AVAILABLE

This is to certify that the facilities for work on the subject of thesis titled **"TO COMPARE ENDOTHELIAL CELL COUNT AT 1 YEAR BETWEEN FULL THICKNESS AND LAMELLAR CORNEAL TRANSPLANT"** exist in the Department of Ophthalmology, DMC&H, Ludhiana and will be provided to the candidate. We will see that the data being included in the thesis is genuine and is collected by the candidate herself under our supervision and guidance.

Supervisor

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APPROVAL PROFORMA
BY
RESEARCH & ETHICAL COMMITTEE
DAYANAND MEDICAL COLLEGE & HOSPITAL, LUDHIANA

Name of candidate	Dr. Chandandeep Kaur Gill
Department	Ophthalmolology
Topic of Thesis	To compare Endothelial cell count at 1 year between Full thickness and Lamellar corneal transplant
Likely date of appearing in PG examination	May 2022
Date of enrollment	04th May, 2017
Name of Head of Department	Dr. Sumeet Chopra
1) Supervisor **2) Co-Supervisor(s)**	Dr. Sumeet Chopra Dr. Priyanka Arora Dr. Sahil Goel
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Dr. Jaspal Singh (Professor & Head, Surgery)	Mr. A K Jindal (Member, Ethics Committee)
Dr. Dinesh Gupta (Professor & Head, Medicine)	Dr. Anu Sharma (Professor, Anatomy)
Dr. Sandeep Kaushal (Assistant Dean Academics)	Dr. Deepinder K Chhina (Professor & Head, Microbiology)
Dr. Rajoo Singh Chhina (Dean Academics)	Dr. Neena Sood (Professor & Head, Pathology)
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Approved: Yes / ~~No~~

Dr. Sandeep Puri
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Research Committee

Chairperson
Research Committee

Approved: Yes / ~~No~~

Prof. Arvind Malhotra
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BABA FARID UNIVERSITY OF HEALTH SCIENCES, FARIDKOT

PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

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2	NAME OF THE INSTITUTE	Dayanand Medical College & Hospital, Ludhiana
3	COURSE OF STUDY AND SUBJECT	MS Ophthalmology
4	DATE OF ADMISSION OF COURSE	04-05-2019
5	TITLE OF THE TOPIC	TO COMPARE ENDOTHELIAL CELL COUNT AT 1 YEAR BETWEEN FULL THICKNESS AND LAMELLAR CORNEAL TRANSPLANT

6. BRIEF RESUME OF THE INTENDED WORK

6.1 NEED FOR THE STUDY

Cornea is a complex avascular transparent structure. It is responsible for three quarters of refractive power of the eye. Corneal endothelium plays a major role in maintaining the optical transparency of the cornea. The crystalline organization and critical spacing of collagen fibrils makes cornea transparent.[1] Any accumulation of fluid would disrupt this spacing and degrade the transparency.

The principle physiological function of the corneal endothelium is to allow leakage of solutes and nutrients from the aqueous humor to the more superficial layers. It contains active pump mechanism to cause extrusion of sodium and water from the stroma and thus plays an important role in maintaining corneal transparency.

Full thickness corneal transplant is mainly done in conditions like stromal opacities, corneal perforation from infection, keratoconus and in various corneal dystrophies and degenerations.In anterior lamellar corneal transplant, only stroma is replaced and it preserves the endothelium, therefore eliminates the risk of endothelial graft rejection.

Corneal endothelium plays an important role in long term survival of the graft. Although, It is a normal phenomenon that endothelial cell density decreases with ageing in normal cornea but the rate of endothelial cell loss following full thickness corneal transplant is reported to be about 33% within the first two years, about 54% for the first three years and between 59% and 70% at the end of the fifth year.[2]These rates are significantly higher than the normal physiologic rate of endothelial cell loss which is about 0.6% per year.[3]

Anil kubaloglu et al studied and compared the status of corneal endothelium and central corneal thickness within the first four postoperative years after deep anterior lamellar keratoplasty (DALK) and penetrating keratoplasty (PK) in patients with keratoconus.Study concluded that corneal endothelial cell loss in the DALK group occurs at a slower rate than in the PK group suggests DALK as a safer alternative to PK in these selected patients.[4]

Ang M et al [5] studied and compared endothelial cell (EC) loss and graft survival after Descemet's stripping automated endothelial keratoplasty (DSAEK) and conventional penetrating keratoplasty (PK) in Asian eyes.

Consecutive patients who underwent DSAEK or PK with Fuchs' endothelial dystrophy or pseudophakic and aphakic bullous keratopathy (BK) at a single tertiary center from April 1, 2006, to April 1, 2008.study concluded that Compared with PK, DSAEK resulted in lower EC loss with comparable cumulative graft survival rates for up to 3 years in patients with Fuchs' dystrophy and BK.

Therefore, we aims to compare the endothelial cell loss in patients of full thickness and lamellar corneal transplant after 1 year of follow up.

6.2 REVIEW OF LITERATURE

Anil kubaloglu et al [4] studied and compared the status of corneal endothelium and central corneal thickness within the first four postoperative years after deep anterior lamellar keratoplasty (DALK) and penetrating keratoplasty (PK) in patients with keratoconus.Thirty-nine eyes (Group A) which had PK and 44 eyes (Group B) which had DALK for the treatment of keratoconus were included in this retrospective study. The endothelial cell density (ECD), the mean endothelial cell area and the coefficient of variation of cell area were assessed with a non-contact specular microscope, and the central corneal thickness (CCT) was measured with an ultrasound pachymeter.This study concluded that corneal endothelial cell loss in the DALK group occurs at a slower rate than in the PK group suggests DALK as a safer alternative to PK in these selected patients.

Bertelmann et al [6]conducted a study on risk factors for endothelial cell loss.The aim of this study was to determine the rate of endothelial cell loss in our patients and to detect dependencies on donor- and recipient-related factors.Using non-contact specular microscopy, endothelial cell counts were ned every 6 months from 293 consecutive patients who underwent keratoplasty between 1996 and 2000. Follow-up time was 36 months. This study shows that preoperative glaucoma is a major risk factor for increased endothelial cell loss following keratoplasty.

Price Mo et al [7]conducted a study to assess 3-year outcomes of Descemet's stripping automated endothelial keratoplasty (DSAEK) in comparison with penetrating keratoplasty (PKP) from the Cornea Donor Study (CDS). The DSAEK procedures were performed by 2 experienced surgeons using the same donor and similar recipient criteria as for the CDS PKP procedures, performed by 68 surgeons. Graft success was assessed by Kaplan-Meier survival analysis. Central endothelial cell density (ECD) was determined from baseline donor and postoperative central endothelial images by the reading center used in the CDS Specular Microscopy Ancillary Study.Study found that the

for DSAEK and PKP procedures. A 5-mm DSAEK incision width was associated with significantly less cell loss than a 3.2-mm incision.

Bart Van Dooren et al [8]conducted a study to report the midterm endothelial cell density measurements after posterior lamellar keratoplasty (Melles techniques).Fifteen consecutive eyes of 15 patients in whom a posterior lamellar keratoplasty procedure was performed for pseudophakic bullous keratopathy or Fuchs' endothelial dystrophy were evaluated. In 11 corneas the donor tissue was inserted through a 9.0-mm sclerocorneal pocket incision (technique A); in four cases the donor was folded and inserted through a 5.0-mm incision (technique B). Specular microscopy was performed at 6, 12, 24, and 36 months after surgery, to measure the endothelial cell density.Study concluded that in posterior lamellar keratoplasty, the donor corneal endothelium showed a decrease in cell density similar to that after conventional full-thickness penetrating keratoplasty.

Ku BI et al [9]conducted a study to compare endothelial cell density (ECD) loss rates in penetrating keratoplasty (PKP), Descemet's stripping automated endothelial keratoplasty (DSAEK), and deep anterior lamellar keratoplasty (DALK).Patients who received PKP, DSAEK, or DALK from 2009 to 2014 were analyzed (68 vs. 38 vs. 11 patients, respectively). Only clear grafts and initial ECD more than 1000 cell/mm2 were included in the study. The main outcome was ECD loss rate. The follow-up time period was divided into five subgroups: 0-1.5 months, 1.5-6 months, 6-12 months, 12-24 months, and longer than 24 months.According to the study Although ECD loss rate in the DSAEK group was initially larger than that in the PKP group, the DSAEK group possessed better long-term endothelial cell survival rate. The DALK group had a lower ECD loss rate than that of the other groups and maintained a stable ECD at 1 year after surgery.

Khattak A et al[10]conducted a study to assess to compare visual acuity, refraction, topography, and complications of deep anterior lamellar keratoplasty (DALK) and penetrating keratoplasty (PKP) performed in patients with keratoconus (KCN).In this retrospective interventional non-randomized clinical study, patients with moderate to

severe KCN that underwent either PKP or DALK for optical corrections were enrolled. The final outcome analysis was performed after complete suture removal for both groups of patients. Best corrected visual acuity, spherical equivalent, refractive cylinder, average keratometry, corneal astigmatism, and endothelial cell density as well as early and late complications such as cataract, glaucoma, corneal edema, elevated intraocular pressure without visual field defect or optic disk changes, rejection, loose suture, and re-suturing were compared.According to this study the vision, refractive error, and corneal astigmatism following DALK and PKP were comparable; however, DALK had lower incidence of long-term complications.

According to ***Maier P et al*** [11] study in 2009,Deep anterior lamellar keratoplasty (DALK) avoids the risk of endothelial immune reactions. However, visual outcomes are comparable to PKP only is complete baring of Descemet's membrane is achieved. In Descemet stripping (automated) endothelial keratoplasty [DS(A)EK], a variation of posterior lamellar keratoplasty, only the diseased endothelium is removed with the Descetmet membrane (descemetorhexis). The lamellar, endothelium-bearing graft can subsequently be implanted via a corneoscleral/corneal tunnel, whereby little astigmatism is induced. The main advantage of DS(A)EK compared to PKP is faster visual recovery with almost unaltered refraction, although visual acuity is often slightly lower.

Krumeich JH et al [12] conducted a study to know whether DALK is an equal or better alternative to penetrating keratoplasty (PKP) given all indications with intact corneal endothelium. A consecutive series on 166 eyes is compared to a group of 566 consecutive PKP eyes regarding visual acuity, astigmatism, stability of refraction and endothelial cell count. The operations were performed in one centre by the same surgeon with the same trephine (Guided Trephine System, GTS) and special instrumentation for DALK (Geuder, Heidelberg). All transplants were of a diameter of 8 mm, the fixation was done with the double-running antitorque suture with one exception. All cases of DALK and PKP were analysed first as two overall groups, then subgroups

were broken down for keratoconus and endothelial cell counts (ECC). The subgroups comprised 135 DALK and 76 PKP eyes.According to this study,there is no clinical difference in the outcomes of BCVA or cylinders it must be concluded that with the data presented the DALK operation should be preferred over PKP in eyes that preoperatively have normal endothelial cell counts.

Bahar I et al [13] conducted a study to describe the visual outcomes and intraoperative and postoperative complications after penetrating keratoplasty (PK), deep lamellar endothelial keratoplasty (DLEK), Descemet stripping endothelial keratoplasty (DSEK), and Descemet stripping automated endothelial keratoplasty (DSAEK) and to compare the results with those of previously reported series.One hundred seventy-seven eyes of 161 consecutive patients who had corneal edema resulting from Fuchs endothelial dystrophy, pseudophakic bullous keratopathy, aphakic bullous keratopathy, failed graft or iridocorneal endothelial syndrome.Study found that The DSAEK surgery enabled rapid and better UCVA and BSCVA when compared with PK, DLEK, and DSEK, with significantly lower astigmatism. Endothelial cell loss was similar, but the dislocation rate was significantly higher in the DSAEK group.

Borderie VM et al [14] studied and compared deep anterior lamellar keratoplasty (DALK) with penetrating keratoplasty (PK) in eyes with corneal diseases not involving the corneal endothelium (keratoconus, scars after infectious keratitis, stromal dystrophies, and trauma).One hundred forty-two consecutive DALK (DALK group; big-bubble technique or manual lamellar dissection using a slitlamp) and 142 matched PK (PK group).According to the study long-term, model-predicted graft survival and endothelial densities are higher after DALK than after PK. Compared with PK, manual dissection provides higher survival of both the corneal endothelium and graft, but lower visual acuity.

Liu M et al [15] studied to review the risk factors and pathogenesis of endothelial decompensation after penetrating keratoplasty (PKP) and its novel therapeutic strategies. According to this study any direct or

indirect damage to the endothelium could cause the loss, morphological changes, and dysfunction of endothelial cells. Graft size, indications, and recipient glaucoma or glaucoma surgery history are risk factors for endothelial decompensation. DSAEK and DMEK are novel therapeutic strategies for failed PKP grafts and have potential superiorities compared with repeat PKP.

Cheng J et al [16] studied and compared the therapeutic effects of penetrating keratoplasty (PK) and deep anterior lamellar keratoplasty (DALK) on patients with macular corneal dystrophy (MCD) and to analyze the risk factors of postoperative recurrence.Fifty-one patients (78 eyes) with MCD treated by PK or DALK at Shandong Eye Institute between January 1992 and December 2010.According to this study, Penetrating keratoplasty more often immediately improves the visual acuity of patients with MCD, but many complications seem to be inevitable, especially continuous loss of corneal endothelium. Despite poor visual acuity and recurrence after surgery, DALK may produce fewer complications overall and more durable stability of the ocular surface compared with PK.

Sharma RA et al [17] compared the effect of Descemet's stripping endothelial keratoplasty (DSEK) with penetrating keratoplasty (PKP) on intraocular pressure (IOP) and use of ocular antihypertensives.Thirty-five eyes in 33 patients undergoing PKP and 43 eyes in 38 patients undergoing DSEK were included in the analysis. Fifteen eyes undergoing PKP and 12 undergoing DSEK had diagnosed glaucoma. Patients undergoing corneal transplant because of trauma, keratoconus, pellucid marginal degeneration, or prior failed transplant were excluded. According to this study, Elevation of IOP requiring treatment occurred at a lower rate after DSEK compared with PKP. This difference was significant during the early postoperative course but nonsignificant at 24 weeks.

A Vong et al [18] studied and measured long,term endothelial cell loss (ECC) following penetrating keratoplasty (PKP) for keratoconus (KCN). ECC was measured in eyes that had PKP from 1994-2008 for KCN. Only eyes with clear grafts were analyzed. ECC was compared to

the original donor ECC.This study concluded that here is continuing long-term ECC loss years after PKP with the greatest loss in the first 5 years following surgery. Corneal clarity and visual acuity were not affected. Compliant patients without complicating factors had best corrected vision of 20/40 or better. Cataract surgery, refractive surgery, and resolved rejection episodes also led to continued endothelial cell loss but did not affect corneal clarity.

6.3 AIMS AND OBJECTIVES OF THE STUDY

To compare the endothelial cell count in patients at 1 year follow up after Full thickness and Lamellar Corneal Transplant.

7. MATERIALS AND METHODS

This study aims to compare the endothelial cell count in patients at 1 year follow up after Full thickness and Lamellar Corneal Transplant.

7.1 Source of Data

A retroprospective study, subjects will be recruited from the Ophthalmology outpatient services at Dayanand Medical College and Hospital from January 2019 to June 2021.

1.2. METHOD OF COLLECTION OF DATA

Two groups will be formulated.

GROUP A comprising of Full thickness corneal transplant patients

GROUP B comprising of Lamellar corneal transplant patients

INCLUSION CRITERIA

All the patients with history of corneal transplant will be included

EXCLUSION CRITERIA

Graft with persistent epithelial defect

Significant scarring and Interface Haze in graft not permitting Specular microscopy.

Ophthalmology examination including a complete history, slit lamp examination, specular microscopy will be done.

Noncontact specular microscopy (CEM-530 NIDEK) will be performed, using an autofocus device, to assess the corneal endothelial status, and the endothelium will be visualized on an incorporated screen. Automated method will be tried first, If not successful then manual method will be tried. The centres of contiguous cells will be marked, after which the computer will calculate and display the endothelial cell density (cells/mm2) and analyze the number of cells. Specular microscopy will be done at 1 year.

Outcome:

PRIMARY OUTCOME

Endothelial cell count in Full thickness and Lamellar keratoplasty

Statistical Analysis

Data will be described in terms of range; mean ±standard deviation (± SD), median, frequencies (number of cases) and relative frequencies

(percentages) as appropriate. Comparison of quantitative variables between the study groups will be done using Student t-test and Mann Whitney U test for independent samples for parametric and non-parametric data respectively. For comparing categorical data, Chi square ($\chi 2$) test will be performed and exact test was used when the expected frequency is less than 5. A probability value (p value) less than 0.05 will be considered statistically significant. All statistical calculations will be done using SPSS (Statistical Package for the Social Science) SPSS 21 version statistical program for Microsoft Windows.

7.3 DOES THE STUDY REQUIRE ANY INVESTIGATIONS OR INTERVENTIONS TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS? IF SO, PLEASE DESCRIBE BRIEFLY.

Specular microscopy

7.4 HAS ETHICAL CLEARANCE BEEN OBTAINED FROM YOUR INSTITUTION IN CASE OF 7.3?

Attached herewith.

8. REFERENCES

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PROFORMA

Sr no

Name

Age/ Sex MRD no.

Father's / Husband's name

Address

Occupation

Chief complaints

History of corneal transplant

- Date
- Type

☐ Lamellar keratoplasty ☐ Therapeutic keratoplasty ☐ Optical keratoplasty

Ocular examination Right Left

- visual acuity (BSCVA)

Slit lamp examination

- conjunctiva
- cornea
- anterior chamber
- pupils
- lens
- Baseline Endothelial cell count (eye bank)

	12 months
BSCVA	
Goldmann applanation tonometry	
Endothelial cell count	
Endothelial cell density	
Coefficient of variation	
Hexagonality	

Signature of Candidate **Signature of Supervisor**

INFORMED PATIENT CONSENT

Date: _____

I.....D/o, W/o, S/o..... .....am willing to participate in the study **"TO STUDY THE CENTRAL CORNEAL THICKNESS, CORNEAL ENDOTHELIAL CELL DENSITY AND MORPHOLOGY IN CASES WITH DIABETES MELLITUS"** The procedure with its complications has been explained to me in local vernacular language. I have fully understood that no special tests and extra expenditure in any form, merely for the purpose of thesis is being carried out. I am free to opt out the study any time without assigning any reason.

....

Signature of the Witness Signature of the patient

Name:

Signature of Candidate **Signature of Supervisor**

मरीज अनुमति फार्म

तिथि _____

मैं_____पत्नी/पुत्र/पुत्री _____

निवासी _____

इस शोधकार्य **"TO STUDY THE CENTRAL CORNEAL THICKNESS, CORNEAL ENDOTHELIAL CELL DENSITY AND MORPHOLOGY IN CASES WITH DIABETES MELLITUS"** में भाग लेने के लिए सहमत हूँ। मैं इस शोधकार्य में भाग लेने के लिए अपनी स्वेच्छा से तैयार हूँ। मैं पुष्टि करता/करती हूँ की यह स्वीकृति देने के लिए मुझे कोई आर्थिक प्रलोभन नहीं दिया गया और न ही दबाव डाला गया है। मुझे इस शोधकार्य का उद्देश्य स्पष्ट कर दिया गया है और मुझे यह विश्वास है की यह विज्ञान और मानवता के लाभ के लिए है। मुझे इस शोधकार्य में होने वाले जोखिम के बारे में समझा दिया गया है और मेरी समझ में यह जोखिम बहुत मामुली है।

मैं इस शोधकार्य में भाग लेने के सम्बन्ध में किसी भी समय अपनी अस्वीकृति व्यक्त कर सकता/सकती हूँ और मेरे अस्वीकृति व्यक्त करने का मेरे इलाज पर कोई प्रभाव नहीं पड़ेगा।

_____ _____

गवाह के हस्ताक्षर रोगी के हस्ताक्षर/अंगूठे का निशान

नाम: नाम:

_____

अन्वेषक के हस्ताक्षर

_____

विद्यार्थी के हस्ताक्षर

ਮਰੀਜ਼ ਰਜ਼ਾਮੰਦੀ ਫਾਰਮ

ਮਿਤੀ_____

ਮੈ_____ਪਤਨੀ/ਪੁੱਤਰ/ਪੁੱਤਰੀ_____

ਵਾਸੀ _____

"TO STUDY THE CENTRAL CORNEAL THICKNESS, CORNEAL ENDOTHELIAL CELL DENSITY AND MORPHOLOGY IN CASES WITH DIABETES MELLITUS" ਤੇ ਚਲ ਰਹੀ ਖੋਜ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਰਜ਼ਾਮੰਦ ਹਾਂ। ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਮੈ ਆਪਣੀ ਮਰਜ਼ੀ ਨਾਲ ਤਿਆਰ ਹਾਂ। ਮੈ ਇਹ ਦਸਣਾ ਚਾਹੁੰਦਾ ਹਾਂ/ ਚਾਹੁੰਦੀ ਹਾਂ ਕੇ ਇਹ ਰਜ਼ਾਮੰਦੀ ਦੇਣ ਵਾਸਤੇ ਮੈਨੂ ਕਿਸੇ ਵੀ ਤਰਾਂ ਦਾ ਲੋਭ-ਲਾਲਚ ਨਹੀ ਦਿੱਤਾ ਗਿਆ ਅਤੇ ਨਾ ਹੀ ਕੋਈ ਦਬਾ ਪਾਇਆ ਗਿਆ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਦਾ ਮਨੋਰਥ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਭਰੋਸਾ ਦਵਾਇਆ ਗਿਆ ਹੈ ਕੇ ਇਹ ਖੋਜ ਵਿਗਿਆਨ ਅਤੇ ਮਾਨਵਤਾ ਦੀ ਭਲਾਈ ਲਈ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਵਿਚ ਹੋਣ ਵਾਲੇ ਖਤਰੇ ਬਾਰੇ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਯਕੀਨ ਹੈ ਕੇ ਇਹ ਖਤਰਾ ਬਹੁਤ ਮਾਮੂਲੀ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਦਾ ਢੰਗ – ਤਰੀਕਾ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ।

ਮੈ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਬਾਰੇ ਆਪਣੀ ਰਜ਼ਾਮੰਦੀ ਕਿਸੇ ਵੀ ਸਮੇ ਵਾਪਸ ਲੈ ਸਕਦਾ ਹਾਂ/ ਸਕਦੀ ਹਾਂ ਅਤੇ ਮੇਰੀ ਰਜ਼ਾਮੰਦੀ ਵਾਪਸ ਲੈਣ ਦਾ ਮੇਰੇ ਇਲਾਜ ਤੇ ਕੋਈ ਅਸਰ ਨਹੀ ਹੋਵੇਗਾ।

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ਗਵਾਹ ਦੇ ਹਸਤਾਖਰ ਮਰੀਜ਼ ਦੇ ਹਸਤਾਖਰ

ਮਿਤੀ_____ ਮਿਤੀ_____

ਪਤਾ _____ ਪਤਾ _____

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ਨਿਰੀਖਕ ਦੇ ਹਸਤਾਖਰ

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ਸਿਖਿਆਰਥੀ ਦੇ ਹਸਤਾਖਰ